REMARKS

The Office Action has been carefully considered and the foregoing amendment made in response thereto. The present status is as follows:

- Claims 1-8, 10, and 12-26 are pending in the application.
- Claims 1-8, 10, and 12-26 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and lacking an enabling disclosure.
- Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Floyd (U.S. Pat. No. 4,904,450).
- Claims 1-8, 10, 12-23, 25, and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Moore (U.S. Pat. No. 5,855,289) in view of Maggio (U.S. Pat. No. 4,859,610) or Babson (U.S. Pat. No. 4,639,242).
- Claim 24 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Moore (U.S. Pat. No. 5,855,289) in view of Maggio (U.S. Pat. No. 4,859,610) or Babson (U.S. Pat. No. 4,639,242), and in further view of Neeley et al. (U.S. Pat. No. 5,164,575).

In view of the above amendment and following remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-8, 10, and 12-26.

1. Claims 1-8, 10, and 12-26 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and lacking an enabling disclosure. Applicants respectfully traverse this rejection as it applies to the claims as amended.

The Office Action maintains that the term "planar" is not disclosed in the specification and that there "is *no mention* of an outwardly extending planar, or flat portion" of the anti-rotation lug 18. Office Action, p. 2 (emphasis in original). The Office Action also states that "[t]here is no mention of the *lowermost edge* of the lug within the specification." *Id.* (Emphasis in original.)

As to the issue regarding the term "planar," the Office Action repeats, essentially verbatim, its previous position with respect to the previous Office Action (mailed 14-Aug-01). Further, the instant Office Action refers to "... lugs 15 (sic.13) ..." in the discussion of Floyd (U.S. Pat. No. 4,904,450). Office Action, p. 8. It appears that the Office Action is simply repeating text that appeared in the prior Office Action that referred to Applicants' inadvertent

typographical error in their 15-Jun-01 Preliminary Amendment. Applicants make no reference to lugs using the incorrect reference designator 13 in their last Amendment and Response (dated 19-Oct-01).

Applicants respectfully contend that, in their Amendment and Response of 19-Oct-01, they have clearly and completely rebutted the rejection of claims 1-8, 10, and 12-26 under 35 U.S.C. § 112, first paragraph (lack of adequate written description with respect to the term "planar"). Specifically, Applicants have directed the Examiner's attention to certain figures, present in the instant application, as filed, that clearly describe and convey the limitations added to the claims during prosecution of the instant application. Referring to Figures 1 and 2 (Figure 2 reproduced at right), for example, the planar (i.e., flat) longitudinally disposed surface (of an anti-rotation lug 18) extending radially outwardly from the outer surface of the body 12 is clearly visible. To facilitate the Examiner's inspection of this drawing and its many features, Applicants have denoted in the enlarged portion of Figure 2 below the longitudinally disposed surfaces on anti-rotation lugs 18 that are present. As the annotations show, the planar (i.e., flat) characteristic is clearly visible.

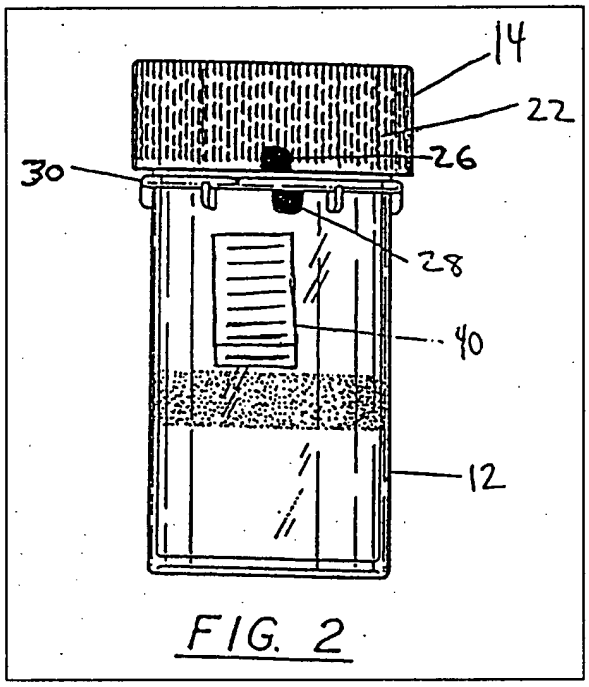
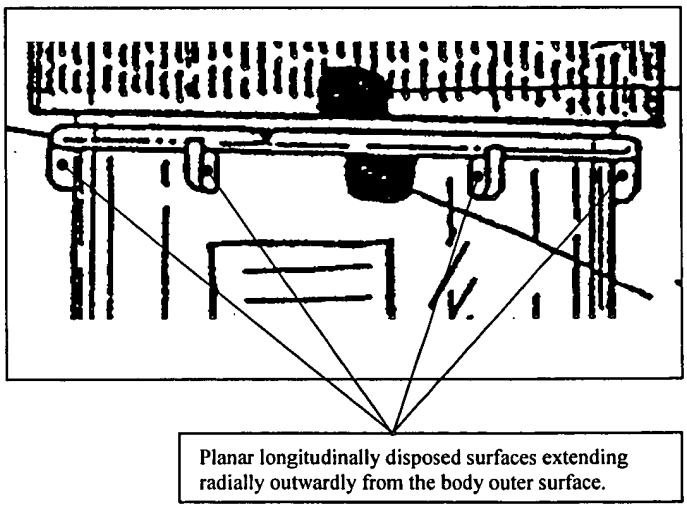


FIG. 2



The Examiner's assertion that there is "no mention of an outwardly extending, 'planar' or flat portion" of the anti-rotation lug is not understood. As shown in the drawings above, Applicants clearly and unequivocally included in their application, as filed, disclosure of the planar (i.e., flat) characteristic of the longitudinally disposed surface that comprises the anti-rotation lug 18.

Further, Applicants, in their previous Amendment and Response (dated 19-Oct-01), cited applicable case law supporting their position that a drawing may, by itself, constitute a written description of the invention if it reasonably conveys to one of ordinary skill that the inventor possessed the invention. It is well settled that "satisfaction of the 'written description' requirement does not require in haec verba antecedence in the originally filed application." *Staehelin v. Secher*, 24 USPQ 2d 1513, 1519 (B.P.A.I. 1992). Consequently, a specific (textual) "mention" of the limitation in the specification is not required to satisfy 35 U.S.C. § 112, first paragraph.

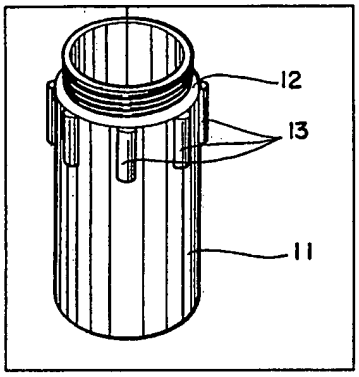
To facilitate the Examiner's analysis of Applicants' position, Applicants have attached hereto as Appendices A, B, and C the following cases, with the pertinent portions highlighted, that support their position on the issue of satisfying the written description requirement based on disclosure present in the drawings:

- *Vas-Cath, Inc. v. Mahurkar,* 19 USPQ 2d 1111, 1118 (Fed. Cir. 1991).
- *Ex parte Parks*, 30 USPQ 2d 1234, 1236–37 (B.P.A.I. 1993).
- *Staehelin v. Secher*, 24 USPQ 2d 1513, 1519 (B.P.A.I. 1992).

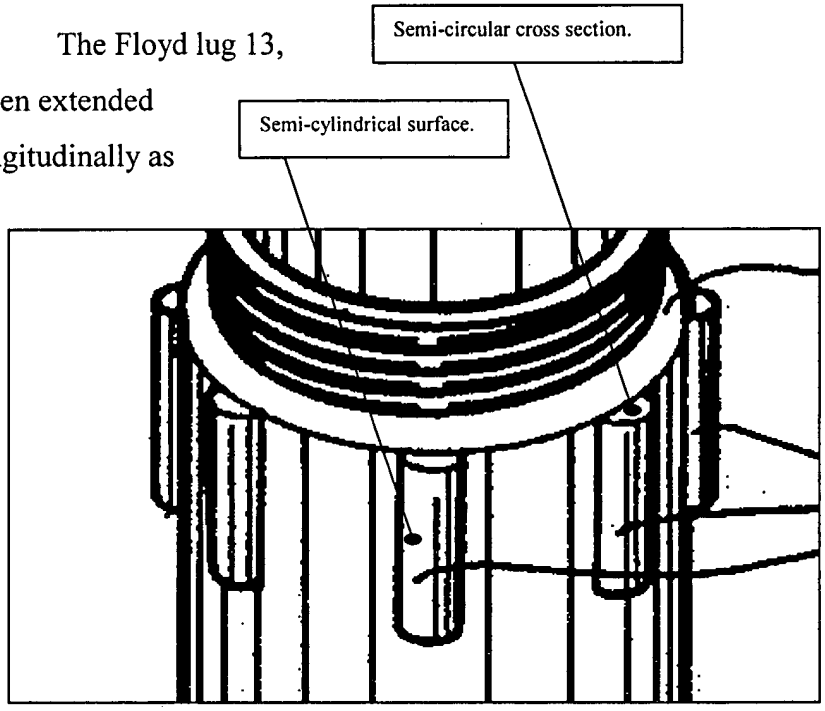
Applicants further direct the Examiner's attention to the "Revised Interim Written Description Guidelines Training Materials" supplied by the U.S. Patent and Trademark Office and available on the Internet at http://www.uspto.gov/web/menu/written.pdf (copy attached hereto as Appendix D). Example five, discussed at pages 24-26 therein, illustrates a scenario where "a review of the specification shows that the claimed invention has been reduced to drawings" where "one skilled in the relevant art would understand what is intended and how to carry it out." This example concludes that the "claimed invention has been adequately described."

Further, with respect to the planar issue, the Office Action states that the "Examiner believes that the lugs 13 [of Floyd, U.S. Pat. No. 4,904,450] are indeed 'planar and longitudinally disposed'." Applicants respectfully disagree. Applicants have claimed the planar (i.e., flat) characteristic of the longitudinally disposed surface which forms a side of the anti-rotation lug 18. This clearly structurally distinguishes the claimed lug from the Floyd disclosure. In fact,

Floyd Figure 2 (excerpted below at left) shows the Floyd lug 13 in external perspective, clearly illustrating, as shown in the enlarged portion of the figure shown at right, its contoured semi-cylindrical, non-planar (i.e., non-flat) surface.



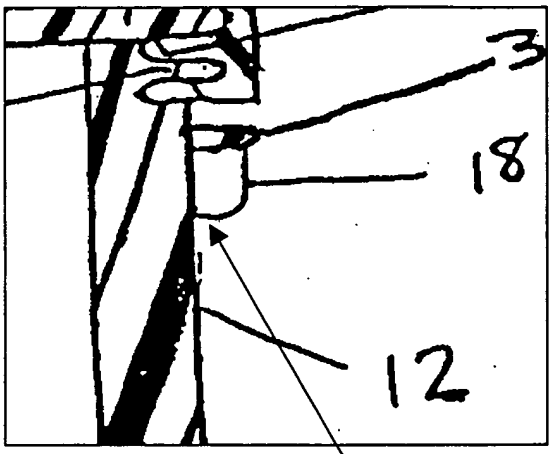
The Floyd lug 13, when extended longitudinally as shown, has a semi-cylindrical surface resulting from the semi-circular cross section. This is clearly evident in the Floyd figures and is readily distinguishable from Applicants' anti-rotation lug 18 having a planar (i.e., flat) longitudinally disposed surface extending radially outwardly from the outer surface of the body 12.



Applicants have consistently used the term "planar" in a manner consistent with its common usage and dictionary definition, namely "flat." *The American Heritage® Dictionary of the English Language, Fourth Edition,* Houghton Mifflin Company, 2000. The Examiner has refused to allow Applicants to adopt this definition. To advance beyond this impasse, Applicants have amended claim 1 to replace the term "planar" with the term "flat." As discussed at length above in conjunction with the synonymous term "planar" and, as can be appreciated from Applicants' Figure 2, this does not represent new matter.

In their last Amendment and Response (dated 19-Oct-01), Applicants amended claim 1 to include a lowermost edge of the longitudinally disposed surface that is substantially perpendicular to the outer surface of the body 12. The assertion in the Office Action that "[t]here is no mention of the *lowermost edge* of the lug within the specification" (Office Action, p. 3;

emphasis in original) is similarly traversed for the reasons discussed above. Referring to Applicants' Figure 5 (a portion of which is reproduced in enlarged fashion below), it is clear that the substantially perpendicular lowermost edge was in fact disclosed in the instant application, as filed. Accordingly, the reasons stated above in rebuttal to the assertion of inadequate written description with respect to disclosure of the planar (i.e., flat) characteristic also apply equally well here. Namely, the requirements of 35 U.S.C. § 112, first paragraph, may be fulfilled by the disclosure in the drawings. It is clear that in the instant case Applicants' application, as filed, included drawings disclosing that the lowermost edge of the of the longitudinally disposed surface is substantially perpendicular to the outer surface of the body 12. The authority discussed above supports Applicants' position that there is no requirement that Applicants (textually) "mention" the lowermost edge in the instant specification, as the Examiner suggests.



The lowermost edge of the longitudinally disposed surface is substantially perpendicular to the outer surface of the body 12.

With respect to the rejection of claims 1-8, 10, and 12-26 under 35 U.S.C. § 112, first paragraph, as lacking an enabling disclosure, Applicants submit that the Office Action does not present a *prima facie* case of nonenablement. Specifically, the Office Action fails to provide a rational basis as to why the disclosure does not teach (or why to doubt the objective truth of the statements in the disclosure that purport to teach) the manner and process of making and using the invention that corresponds to the scope of the claimed invention to one of ordinary skill in the pertinent technology, without undue experimentation, and dealing with subject matter that would not already be known to the skilled person as of the filing date of the application. The Office Action does not provide evidence from the application of each of these elements, as required to support an enablement rejection under 35 U.S.C. § 112, first paragraph. Rather, the Office Action simply focuses on Applicants' purported failure to "mention" the planar (i.e., flat) and lowermost substantially perpendicular edge characteristics of the longitudinally disposed surface of an anti-rotation lug 18. As stated above, it is Applicants' position that their figures, as filed,

contain adequate disclosure of these characteristics. Applicants further contend that applicable law clearly supports their argument that adequate disclosure for the purpose of 35 U.S.C. § 112 may lie within the figures.

Applicants wish to comment on the statement in the Office Action that "[t]he addition of specific limitations describing the lug appears to be an attempt to carve out subject matter discovered in the prior art violates the description requirement of 35 U.S.C. § 112 on the basis of lack of enablement and lack of description." Applicants do understand the Examiner's position that claimed features must have a basis in the application as filed. Nevertheless, the application as filed includes the specification, claims, and drawings. Support for features added to the claims during prosecution may lie in any of these sources. Applicants have clearly shown that the features added to the claims during the course of this prosecution have had support in drawings as filed. Applicants have highlighted pertinent drawings and cited case law that supports their position allowing one to look to the drawings to satisfy 35 U.S.C. § 112. Finally, and most importantly, Applicants' numerous attempts to add limitations to the claims represent bona fide attempts to advance the prosecution of the instant application. These attempts exemplify the essence of patent prosecution, namely, the addition of further limitations to originally presented broad claims in order to delineate the claimed invention from the prior art. Applicants have merely added further features of the specific embodiments of the invention. The Examiner should not prevent Applicants from prosecuting the instant application in this well-accepted fashion by raising 35 U.S.C. § 112 rejections that (i) ignore the clear and unmistakable teachings of the figures in the instant application, (ii) fail to show the required elements of a *prima facie* case of nonenablement, and (iii) fail to recognize the sources of as-filed disclosure permitted by applicable case law.

Applicants respectfully request reconsideration and withdrawal of the rejection of independent claim 1 and dependent claims 2-8, 10, and 12-26 (all depending, directly or indirectly, from claim 1) under 35 U.S.C. § 112, first paragraph. If the Examiner is inclined to maintain this rejection, Applicants respectfully request that the Examiner address specifically the case law and U.S. Patent and Trademark Office Written Description Guidelines referred to and included herewith. Alternatively, at the request of the Examiner, Applicants would be willing to

amend the specification to specifically recite in the specification the structural features of the lug at issue to overcome this rejection.

2. Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Floyd (U.S. Pat. No. 4,904,450). Applicants respectfully traverse this rejection as it applies to the claims as amended.

As described above and shown in Floyd Figures 2 and 3 (perspective views), Floyd discloses lugs 13 that are semi-cylindrical projections from casement 11. It is evident from these figures that the outer surface of each of Floyd's lugs 13 is curved and not flat as that term is used in claim 1, as amended herein, and as discussed above. Furthermore, Floyd only mentions the lugs in passing at col. 4, l. 16, which identifies the lugs 13, but offers no further details regarding their shape or structure. Consequently, it is clear that Floyd neither teaches nor discloses lugs 13 that have any shape other than semi-cylindrical, as depicted in Floyd Figures 2 and 3.

The flat nature of each anti-rotation lug 18 disclosed and claimed by Applicants is a relevant aspect of Applicants' invention. As discussed in the specification at p. 13, ll. 3-12, during operation of the automated test apparatus, the body 12 is placed in the bore 52. Within the bore 52 are ramps 56, each having a substantially vertical ramp face 58 that, as shown in Figure 7A, is also substantially flat. The abutting flat surface of each anti-rotation lug 18 reacts against a respective ramp face 58 to prevent rotation of the body 12 when the cap 14 is turned. For effective reaction against each ramp face 58, each anti-rotation lug 18 is configured to have a flat surface that makes good contact with the former. If each anti-rotation lug 18 had a non-flat surface, contact with each ramp face 58 would not be optimized, due to the substantially flat configuration of the latter. The reduced contact area reduces the area through which the anti-rotation forces pass between each ramp face 58 and abutting anti-rotation lug 18. This means that, when placed in the bore 52, the body 12 would not be reliably prevented from rotating as the cap 14 is turned. To illustrate, if the anti-rotation lugs 18 had the semi-cylindrical shape as taught by Floyd, only a line contact between each anti-rotation lug 18 and the ramp face 58 would result. During operation of the automated test apparatus, the rotational force applied to the cap 14 by the rotatable interface 42 could cause the anti-rotation lugs 18 to "jump" or bypass

the ramp faces 58, causing the body 12 to rotate in the bore 52. Rotation of the body 12 when in the bore 52 defeats an automation benefit of Applicants' invention.

In view of the above, Applicants respectfully submit that the presence of the term "flat" (i.e., a structural limitation) in claim 1 as amended herein clearly and patentably distinguishes Applicants' invention over Floyd.

Applicants respectfully request reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Floyd.

3. Claims 1-8, 10, 12-23, 25, and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Moore (U.S. Pat. No. 5,855,289) in view of Maggio (U.S. Pat. No. 4,859,610) or Babson (U.S. Pat. No. 4,639,242). Applicants respectfully traverse this rejection as applied to the claims as amended.

Moore teaches the use of ribs 64, 70 on a lid 34 that are adapted to flex under a centrifugal load and expand the peripheral member 38 of the lid 34. Col. 5, ll. 34-36. This expansion increases the sealing force applied by the lid 34, tightening the seal between the gasket 54 and the cylindrical wall 26. Col. 6, ll. 43-47. The downward deflection of the ribs 64, 70 also focuses the compressive force applied by the lid 34 away from the center of the stopper 84 onto the area of the stopper 84 that coincides with the annular ring 68. Col. 7, ll. 18-20. This enhances the fluid-tight and air-tight seal between the stopper 84 and the receptacle 22. Col. 6, ll. 29-35. The mating surfaces of the stopper 84 and the receptacle 22 are smooth, thereby ensuring an effective seal. Moore Figure 7. Thus, the ribs 64, 70 purportedly serve to increase the effectiveness of the two seals when the container 10 is in use. Because the amount of deflection and corresponding expansion increase in proportion to the centrifugal force, the seals are improved as the force increases. As stated in the Office Action, "Moore does not teach the use of at least one anti-rotation lug about the body outer surface." Office Action, p. 5.

Maggio discloses a vessel 1 that is used to contain samples for immunoassays. Col. 1, ll. 8-10; col. 4, ll. 5-11. The outside of the vessel 1 includes support structures 19 that extend along the entire axial length of the vessel 1. Maggio Figures 1-3, 9, and 10. Maggio discusses the support structures 19 only in passing when stating that their purpose is to help a user maintain a

grip on the vessel 1 with one hand while rotating the cap 14 with the other hand. Col. 6, ll. 38-41. Consequently, the support structures must extend the entire axial length of the vessel 1 to provide adequate surface area for gripping. In other words, the support structures 19 must not be so small or of such limited axial extent as to prevent the user from establishing and maintaining a grip on the vessel 1.

Babson discloses outwardly extending vanes 31 disposed about the periphery of a vessel 1. Col. 3, ll. 38-48. The bottom edge of each vane 31 is beveled, resulting in an oblique return of the vane 31 in to the outer wall of the vessel 1. Babson Figure 3. The topmost inner surface of the vessel 1 may be fluted by including V-grooves 32. Col. 3, ll. 66-67; Figure 3. It is this fluted version of the vessel 1 that may be sealed with a tight-fitting cap 41. Col. 3, ll. 49-53; Figure 4. According to Babson, the purpose of the vanes 31 is to interact with a fluid (e.g., a high-speed jet of air) and cause the vessel 1 to spin about its longitudinal axis. *Id.* The spinning creates a centrifugal force that promotes the mixing or separation of the contents of the vessel 1, depending on configuration of the vessel 1 and the rotational speed. Col. 2, ll. 39-45; col. 2, l. 60 – col. 3, l. 7.

The Office Action proposes a combination of Moore with Maggio or Moore with Babson. As to the combination of Moore with Babson, Applicants contend that the result of such a combination renders Moore inoperable for its intended purpose. If, when combined, the references "would produce a seemingly inoperative device," then they teach away from their combination. *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 52 USPQ 2d 1294, 1298 (Fed. Cir. 1999) (quoting *In re Sponnoble*, 160 USPQ 237, 244 (C.C.P.A. 1969)). (Copy attached hereto as Appendix E.)

Combining Moore with Babson would result in a nonfunctional structure, because the sealable version of Babson includes V-grooves 32 that would interfere with the proper sealing action between the smooth mating surfaces as disclosed by the Moore cap structure. The irregular surface formed by the Babson V-grooves 32 would be unable to mate securely with the surface of the Moore stopper 84, thereby compromising the seal integrity. Consequently, a combination of Moore with Babson would be inoperative, as well as destroy the intended function of each reference. Following the rule of *Tec Air*, the proposed combination of Moore

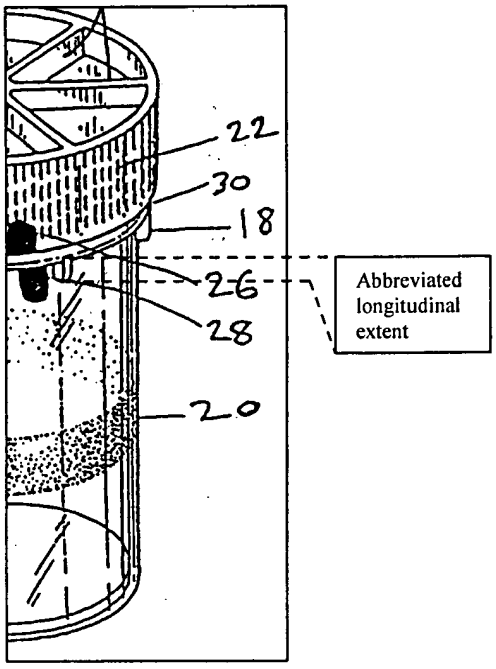
with Babson is not taught, thereby supporting a showing of nonobviousness of Applicants' claimed invention.

The statement in the Office Action that "Applicants' arguments [regarding the sealing action] are not germane to the issue since Babson is relied upon for the teaching of the lugs 31, not the cap structure" (Office Action, p. 9) is misplaced. Prior art references must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention – one cannot pick and choose among individual parts of assorted prior art references "as a mosaic to recreate a facsimile of the claimed invention." *Akzo N.V. v. United States Int'l Trade Comm'n*, 1 USPQ 2d 1241, 1246 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987). (Copy attached hereto as Appendix F.) Accordingly, the Examiner's reliance on Babson for the teaching of lugs 31 necessarily implicates the Babson V-grooves 32. Applicants can rightly argue the incompatibility of the Babson V-grooves 32 with Moore. Consequently, Applicants can properly rebut the proposed combination of Moore with Babson by demonstrating that the resulting combination of the references in their entirety (as required by *Akzo N.V.*) would violate the rule of *Tec Air*.

The proposed alternative combination of Moore with Maggio would not have been obvious to one of ordinary skill in the art at the time of Applicants' invention because there is no reasonable expectation of success for the suggested combination. An invention is nonobvious in view of the prior art when there is no reasonable expectation of success in combining the prior art to arrive at the invention. *In re Vaeck*, 20 USPQ 2d 1438 (Fed. Cir. 1991) (emphasis added). (Copy attached hereto as Appendix G.)

Maggio incorporates support structures 19 that purportedly help the user maintain a grip on the vessel 1. Col. 6, ll. 38-41. The support structures 19, therefore, must be sufficiently large for the user's hand to grasp and maintain a proper grip while the user rotates the cap 14. Consequently, Maggio neither teaches nor discloses support structures 19 having a length other than one coincident with the entire axial length of the vessel 1. Support structures 19 with a lesser length would be difficult for the user to grasp and use as Maggio describes.

In contrast, Applicants' anti-rotation lugs 18 have a significantly abbreviated longitudinal extent that is clearly shown in, for example, Figure 1 (reproduced in enlarged fashion at right). This abbreviated longitudinal extent is a relevant part of Applicants' invention.



During operation, the anti-rotation lugs 18 mate with the unidirectional interface 54 of the bore 52 in a sample vial tray (shown in Figure 7A; reproduced below at right). Specification, p. 13, ll. 3-5. The anti-rotation lugs 18 also mate with the axially extending slots 66 of the vial sleeve 64 (shown in Figure 7B; reproduced below at right). Specification, p. 13, ll. 16-18. In both instances, the abbreviated longitudinal extent of the anti-rotation lugs 18 allows the body 12 to mate with the proximate structure (e.g., the unidirectional interface 54 and the slots 66) at the proper height. In other words, the body 12 seats properly when mated with the proximate structure.

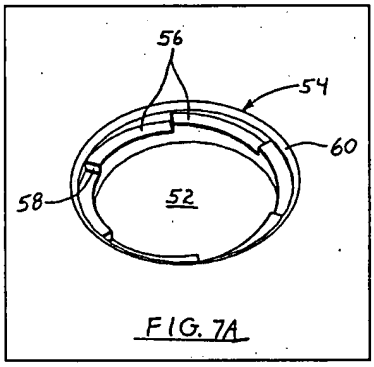


FIG. 7A

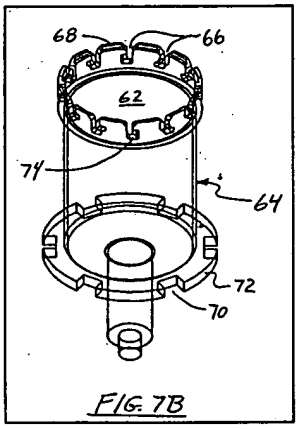


FIG. 7B

If the anti-rotation lugs 18 did not have an abbreviated longitudinal extent, the body 12, when placed in the bore 52 or the vial sleeve 64, would project above the proper seating height. This would create incompatibilities with the automated processing equipment that manipulates the body 12 and cap 14. In the extreme case depicted by Maggio, having lugs that extend the length of the body 12 would, due to their projection outward from the vial, altogether prevent the body 12 from being inserted in either the bore 52 or the vial sleeve 64. This would prevent Applicants' automated processing equipment from operating. Accordingly, any attempt to combine the lugs of Maggio with the sample vial of Moore (Office Action, p. 6) would not result in a functional structure that is Applicants' invention. Following the rule of *In re Vaeck*, the resulting combination Maggio

with Moore neither shows nor suggests the claimed invention. Applicants' invention is clearly nonobvious in view of these references.

Notwithstanding the above, Applicants have amended independent claim 1 to clarify the longitudinal extent of the anti-rotation lugs 18. Specifically, the lowermost edge of the anti-rotation lug 18 is located substantially remote from the closed end of the body 12. This allows for the proper seating of the body 12 in both the bore 52 and the vial sleeve 64. No new matter has been added, since the abbreviated longitudinal extent of the anti-rotation lugs 18 is clearly shown in, for example, Figures 1 and 2 (reproduced above). As discussed above, the figures, as filed, depict the claimed structure of the anti-rotation lugs 18 so as to satisfy 35 U.S.C. § 112, first paragraph.

Applicants respectfully submit that claim 1, as amended herein, is allowable and clearly and patentably distinguished over the cited references, either alone or in combination. Because claims 2-8, 10, 12-23, 25, and 26 all depend, directly or indirectly, from claim 1, Applicants submit that these claims are allowable as well.

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-8, 10, 12-23, 25, and 26 under 35 U.S.C. § 103(a) as being unpatentable over Moore in view of Maggio or Babson.

4. Claim 24 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Moore (U.S. Pat. No. 5,855,289) in view of Maggio (U.S. Pat. No. 4,859,610) or Babson (U.S. Pat. No. 4,639,242), and in further view of Neeley et al. (U.S. Pat. No. 5,164,575). Applicants respectfully traverse this rejection as applied to the claims as amended.

Neely teaches the use of a portable apparatus for blood or other sample collection that places indicia, including a bar code, on a test-tube. Applicants' claim 24 depends from claim 23, which in turn depends from claim 1. Applicants respectfully submit that Neeley fails to cure the deficiencies of Moore, Maggio, and Babson with respect to the structure of the anti-rotation lugs 18 claimed in independent claim 1 as discussed above. Because claim 1, as amended herein, is allowable and clearly and patentably distinguished over the cited references, either alone or in

proper combination, Applicants respectfully submit that claim 24, ultimately depending from claim 1, is allowable as well.

Applicants respectfully request reconsideration and withdrawal of the rejection of claim 24 under 35 U.S.C. § 103(a) as being unpatentable over Moore in view of Maggio or Babson, and in further view of Neeley et al.

CONCLUSION

In view of the foregoing, Applicants submit that claims 1-8, 10, and 12-26, are clearly and patentably distinguished over the cited references, either alone or in proper combination, and are therefore allowable. Applicants respectfully request entry of this Amendment and Response, reconsideration, and early favorable action by the Examiner.

The Examiner is cordially invited to contact Applicants' undersigned representative at the number listed below to discuss any outstanding issues.

Respectfully submitted,

Date: April 2, 2002
Reg. No. 44,691

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APPENDIX 'A'

scope of injunctive relief to the ameliorative steps that it announced at the hearing.[38]

C. *Irreparable Harm*

To obtain preliminary injunctive relief the movant must establish a probability of irreparable harm. In the context of trademark cases, such harm is ordinarily deemed to be established if the movant demonstrates a likelihood of customer confusion as to source or sponsorship. *See, e.g., Home Box Office, Inc. v. Showtime/The Movie Channel, Inc.*, 832 F.2d at 1314; *Standard & Poor's Corp. v. Commodity Exchange, Inc.*, 683 F.2d 704, 708 [216 USPQ 841] (2d Cir. 1982).

For reasons already noted, PAF has offered sufficient evidence of the likelihood of such confusion to establish a probability of success on the merits of this issue at trial. That showing equally satisfies its burden of showing irreparable harm. Moreover, apart from evidence of such likely confusion, PAF introduced evidence suggesting that it may well have already lost a major customer on the West Coast as a result of the similarity of the LTS-619 to the Dove, which is also being marketed in that locale. (Tr. 176-77.) Injury of this type is not likely to be compensable by money damages, and accordingly preliminary injunctive relief is warranted.[39]

D. *The Nature of the Relief to be Awarded*

The scope of relief to be awarded in a case of this type is left, in large measure, to the broad discretion of the trial court. *See, e.g., Soltex Polymer Corp. v. Fortex Indus., Inc.*, 832 F.2d at 1329; *Springs Mills, Inc. v. Ultracashmere House, Ltd.*, 724 F.2d 352, 355 [221 USPQ 577] (2d Cir. 1983). For reasons mentioned, any injunction should be limited to the scope of the harm that is proven, but should be adequate to remedy the injury caused by any proven infringement.

On the current motion, the proven harm appears to be a product of both the striking resemblance of the LTS-619 to the Dove and the way in which both lamps are advertised and marketed. Although as a general matter it is preferable to minimize the degree of injunctive restraint imposed on LTS especially in view of the patented status of its lamp, the current record is inadequate to justify granting relief that falls short of an injunction *pendente lite* against importation or sale of the LTS-619 in its current form. For reasons already noted, LTS has not affirmatively shown that any narrower remedies would suffice to eliminate the serious prospect of significant customer confusion about both the source and the sponsorship of the LTS-619.

Accordingly, LTS, its officers, agents and employees, and all others acting in concert with LTS or its officers, agents and employees, will be enjoined, during the pendency of this lawsuit, from importing or causing to be imported into the United States, and from distributing or selling or promoting, or causing to be distributed, sold or promoted in the United States, the lamps identified by LTS in this proceeding as the LTS-614 and the LTS-619.

There remains the question of whether the injunction should be sufficiently broad to encompass other variations of the same lamp design, which might also infringe the trade dress of the Dove. In view of the prior history of LTS infringement of the Dove trade dress, this prospect cannot be excluded and should not be ignored in defining the scope of the injunction. Nonetheless, a broadly worded prohibition against any other future infringements of the trade dress of the Dove, *e.g., Jolly Time Indus., Inc. v. Elegra Inc.*, 690 F.Supp. at 233, seems inappropriate. First, it would be of questionable utility in defining for LTS the parameters of prohibited conduct. Second, it might have the undesired effect of deterring LTS from continuing to design aesthetically pleasing lamps that may bear some resemblance to products already in the market. To minimize the likelihood of such an adverse effect, the court will instead direct that LTS, its officers, agents and employees and all others acting in concert with LTS and its officers, agents and employees be further enjoined, during the pendency of this lawsuit, from importing or causing to be imported into the United States, and from distributing or selling or promoting, or causing to be distributed, sold or promoted in the United States, any table desk lamp incorporating any of the design features of the LTS-614, the LTS-619 or the Dove, without giving PAF, by its counsel, two weeks written notice before any importation, distribution, sale or promotion, with such notice to include a clear photograph of the new lamp as seen in profile, from the front and from the rear.

PAF is directed to settle an appropriate order within three (3) days embodying the foregoing terms. LTS is to serve and file with the Court within the same time period, one or more affidavits addressing the appropriate amount, if any, of a bond.

SO ORDERED.

[38] This conclusion does not bar LTS from seeking to make such a showing in the future if it seeks relief from any injunction. *See, e.g., HBO, Inc. v. Showtime/The Movie Channel, Inc.*, 832 F.2d at 1316.

[39] Although not required in light of my previous conclusions about the likelihood of success of PAF's Lanham Act Claim, I also find that the record adequately demonstrates that PAF meets the alternative test for injunctive relief, in that the harm it faces if denied relief substantially outweighs the likely harm to LTS if an injunction is entered. The Dove has been shown to be central to PAF's recent commercial success, *see supra* at 4 n.1, and denial of an injunction could undermine that success. In contrast, there is no evidence that the temporary suspension of importation of the LTS-619 would impose any significant hardship on LTS, which appears to sell a wide variety of lamps, as well as auto parts.

Court of Appeals, Federal Circuit

Vas-Cath Inc. v. Mahurkar

Nos. 90-1528, 91-1032

Decided June 7, 1991

JUDICIAL PRACTICE AND PROCEDURE

1. Procedure — Summary judgment — In general (§410.3301)

Procedure — Judicial review — Standard of review — In general (§410.4607.01)

Court of appeals, in reviewing grant of summary judgment, is not bound by federal district court's holding that no material facts are in dispute, and must make independent determination as to whether standards for summary judgment have been met.

PATENTS

2. Patentability/Validity — Specification — Written description (§115.1103)

"Written description" of invention required by first paragraph of 35 USC 112 is separate and distinct from that paragraph's requirement of enabling disclosure, since description must do more than merely provide explanation of how to "make and use" invention; applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed.

3. Practice and procedure in Patent and Trademark Office — Prosecution — Drawings (§110.0920)

Patentability/Validity — Specification — Written description (§115.1103)

Drawings alone may, under proper circumstances, provide "written description" of invention required by 35 USC 112, and whether drawings are from design application or utility application is not determinative.

4. Patentability/Validity — Specification — Written description (§115.1103)

Federal district court erred by requiring drawings from design patent application to "describe what is novel or important" about invention in order to satisfy "written description" requirement of 35 USC 112 for later-filed utility patent on double lumen catheter having combination of features, since there is no legally cognizable or protected "essential" element, "gist" or "heart" of invention in combination patent; rather, invention is defined by claims under consideration.

5. Patentability/Validity — Specification — Written description (§115.1103)

Federal district court erred by considering patents granted to applicant after utility patents containing claims in question in determining whether drawings from design application satisfy "written description" requirement of 35 USC 112 for those claims, since later patenting of inventions having different specifications is irrelevant to determination of Section 112 sufficiency of application in question, which must be judged as of its filing date.

6. Patentability/Validity — Specification — Written description (§115.1103)

Federal district court erred by imposing legal standard that essentially required drawings from design application for double lumen catheter to necessarily exclude all diameters of lumens, other than those within range specified by subsequently-filed utility claims, in order to satisfy "written description" requirement of 35 USC 112 for those claims, since proper test is whether drawings conveyed, with reasonable clarity to those of ordinary skill in art, that applicant had in fact invented catheter having return lumen of diameter within claimed range; defendant's submission of expert's declaration stating that person of ordinary skill viewing drawings would be able to derive claimed range therefrom, and plaintiff's failure to refute such declaration, therefore gave rise to genuine issue of material fact inappropriate for summary disposition.

Particular patents — General and mechanical — Catheters

4,568,329, Mahurkar, double lumen catheter, summary judgment of invalidity reversed.

4,692,141, Mahurkar, double lumen catheter, summary judgment of invalidity reversed.

Appeal from the U.S. District Court for the Northern District of Illinois, Easterbrook, J.; 17 USPQ2d 1353.

Action by Vas-Cath Inc. and Gambro Inc. against Sakharam D. Mahurkar and Quinton Instruments Co., for declaratory judgment of patent non-infringement, in which defendants counterclaim for patent infringement. From entry of summary judgment holding patents invalid, defendants appeal. Reversed and remanded.

William L. Mentlik, of Lerner, David, Littenberg, Krumholz & Mentlik (Roy H. Wepner, John R. Nelson, and Joseph S. Littenberg, with him on brief), Westfield, N.J., for plaintiffs-appellees.

Raymond P. Niro, of Niro, Scavone, Haller & Niro, Chicago, Ill. (Joseph N. Hosteny and John C. Janka, with him on brief; Michael P. Mazza, of counsel); Michael J. Sweedler, of Darby & Darby, New York, N.Y., for defendants-appellants.

Before Rich, Michel, and Plager, circuit judges.

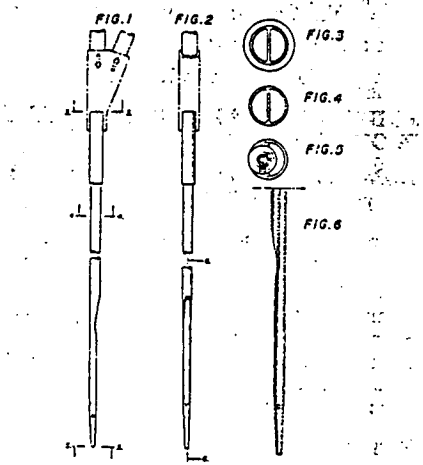
Rich, J.

Sakharam D. Mahurkar and Quinton Instruments Company (collectively Mahurkar) appeal from the September 12, 1990 partial final judgment[1] of the United States District Court for the Northern District of Illinois, Easterbrook, J., sitting by designation, in Case No. 88 C 4997. Granting partial summary judgment to Vas-Cath Incorporated and its licensee Gambro, Inc. (collectively Vas-Cath), the district court declared Mahurkar's two United States utility patents Nos. 4,568,329 ('329 patent) and 4,692,141 ('141 patent), titled "Double Lumen Catheter," invalid as anticipated under 35 USC 102(b). In reaching its decision, reported at 745 F.Supp. 517, 17 USPQ2d 1353, the district court concluded that none of the twenty-one claims of the two utility patents was entitled, under 35 USC 120, to the benefit of the filing date of Mahurkar's earlier-filed United States design patent application Serial No. 356,081 ('081 design application), which comprised the same drawings as the utility patents, because the design application did not provide a "written description of the invention" as required by 35 USC 112, first paragraph. We *reverse* the grant of summary judgment with respect to all claims.

[1] The district court directed entry of final judgment as to the issue of patent invalidity pursuant to Fed.R.Civ.P. 54(b).

BACKGROUND

Sakharam Mahurkar filed the '081 design application, also titled "Double Lumen Catheter," on March 8, 1982. The application was abandoned on November 30, 1984. Figures 1-6 of the '081 design application are reproduced at right [below].



As shown, Mahurkar's catheter comprises a pair of tubes (lumens) designed to allow blood to be removed from an artery, processed in an apparatus that removes impurities, and returned close to the place of removal. Prior art catheters utilized concentric circular lumens, while Mahurkar's employs joined semi-circular tubes that come to a single tapered tip. Advantageously, the puncture area of Mahurkar's semicircular catheter is 42% less than that of a coaxial catheter carrying the same quantity of blood, and its conical tip yields low rates of injury to the blood. The prior art coaxial catheters are now obsolete; Mahurkar's catheters appear to represent more than half of the world's sales. 745 F.Supp. at 520, 17 USPQ2d at 1353-54.

After filing the '081 design application, Mahurkar also filed a Canadian Industrial Design application comprising the same drawings plus additional textual description. On August 9, 1982, Canadian Industrial Design 50,089 (Canadian '089) issued on that application.

More than one year later, on October 1, 1984, Mahurkar filed the first of two utility patent applications that would give rise to the patents now on appeal. Notably, both utility applications included the same drawings as the '081 design application.[2] Serial No. 656,601 ('601 utility application) claimed the benefit of the filing date of the '081 design application, having been denominated a "continuation" thereof. In an Office Action mailed June 6, 1985, the Patent and Trademark Office (PTO) examiner noted that "the prior application is a design application," but did not dispute that the '601 application was entitled to its filing date. On January 29, 1986, Mahurkar filed Serial No. 823,592 ('592 utility application), again claiming the benefit of the filing date of the '081 design application (the '592 utility application was denominated a continuation of the '601 utility application). In an office action mailed April 1, 1987, the examiner stated that the '592 utility application was "considered to be fully supported by applicant's parent application SN 356,081 filed March 8, 1982 [the '081 design application]." The '601 and '592 utility applications issued in 1986 and 1987, respectively, as the '329 and '141 patents, the subjects of this appeal. The independent claims of both patents are set forth in the Appendix hereto.

Vas-Cath sued Mahurkar in June 1988, seeking a declaratory judgment that the catheters it manufactured did not infringe Mahurkar's '329 and '141 utility patents.[3] Vas-Cath's complaint alleged, inter alia, that the '329 and '141 patents were both invalid as anticipated under 35 USC 102(b) by Canadian '089. Vas-Cath's anticipation theory was premised on the argument that the '329 and '141 patents were not entitled under 35 USC 120[4] to the filing date of the '081 design application because its drawings did not provide an adequate "written description" of the claimed invention as required by 35 USC 112, first paragraph.

Mahurkar counterclaimed, alleging infringement. Both parties moved for summary judgment on certain issues, including validity. For purposes of the summary judgment motion, Mahurkar conceded that, if he could not antedate it, Canadian '089 would represent an enabling and thus anticipating §102(b) reference against the claims of his '329 and '141 utility patents. 745 F.Supp. at 521, 17 USPQ2d at 1355. Vas-Cath conceded that the '081 design drawings *enabled* one skilled in the art to practice the claimed invention within the meaning of 35 USC 112, first paragraph. *Id.* Thus, the question before the district court was whether the disclosure of the '081 design application, namely, the drawings without more, adequately meets the "written description" requirement also contained in §112, first paragraph, so as to entitle Mahurkar to the benefit of the 1982 filing date of the '081 design application for his two utility patents and thereby antedates Canadian '089.

Concluding that the drawings do not do so, and that therefore the utility patents are anticipated by Canadian '089, the district court held the '329 and '141 patents wholly invalid under 35 USC 102 (b), *id.* at 524, 17 USPQ2d at 1358, and subsequently granted Mahurkar's motion for entry of a partial final judgment under Fed.R.Civ.P. 54(b) on the validity issue. This appeal followed.

DISCUSSION

The issue before us is whether the district court erred in concluding, on summary judgment, that the disclosure of the '081 design application does not provide a §112, first paragraph "written description" adequate to support each of the claims of the '329 and '141 patents. If the court so erred as to any of the 21 claims at issue, the admittedly anticipatory disclosure of Canadian '089 will have been antedated (and the basis for the court's

[2] The utility patent drawings contain additional but minor shading and lead lines and reference numerals not present in the design application drawings.

[3] Vas-Cath's apprehension of suit apparently arose from a 1988 Canadian action instituted by Mahurkar for infringement of Canadian '089.

[4] Section 120, titled "Benefit of Earlier Filing Date in the United States," provides (emphasis ours):

> An application for patent for an invention *disclosed in the manner provided by the first paragraph of section 112 of this title* in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

grant of summary judgment nullified) as to those claims.

[1] In reviewing the district court's grant of summary judgment, we are not bound by its holding that no material facts are in dispute, and must make an independent determination as to whether the standards for summary judgment have been met. *C.R. Bard, Inc. v. Advanced Cardiovascular Systems*, 911 F.2d 670, 673, 15 USPQ2d 1540, 1542-43 (Fed. Cir. 1990). Summary judgment will not lie if the dispute about a material fact is "genuine," that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

The "Written Description" Requirement of §112

The first paragraph of 35 USC 112 requires that

> [t]he specification shall contain *a written description of the invention*, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(Emphasis added). Application of the "written description" requirement, derived from the portion of §112 emphasized above, is central to resolution of this appeal. The district court, having reviewed this court's decisions on the subject, remarked that "[u]nfortunately, it is not so easy to tell what the law of the Federal Circuit is." 745 F.Supp. at 522, 17 USPQ2d at 1356. Perhaps that is so, and, therefore, before proceeding to the merits, we review the case law development of the "written description" requirement with a view to improving the situation.[3]

The cases indicate that the "written description" requirement most often comes into play where claims not presented in the application when filed are presented thereafter. Alternatively, patent applicants often seek the benefit of the filing date of an earlier-filed foreign or United States application under 35 USC 119 or 35 USC 120, respectively, for claims of a later-filed application. The question raised by these situations is most often phrased as whether the application provides "adequate support" for the claim(s) at issue; it has also been analyzed in terms of "new matter" under 35 USC 132. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the claim(s) corresponding to the count(s) at issue, i.e., whether that party "can make the claim" corresponding to the interference count.

To the uninitiated, it may seem anomalous that the first paragraph of 35 USC 112 has been interpreted as requiring a separate "description of the invention," when the invention is, necessarily, the subject matter defined in the *claims* under consideration. *See In re Wright*, 866 F.2d 422, 424, 9 USPQ2d 1649, 1851 (Fed. Cir. 1989). One may wonder what purpose a separate "written description" requirement serves, when the second paragraph of §112 expressly requires that the applicant conclude his specification "with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

One explanation is historical: the "written description" requirement was a part of the patent statutes at a time *before* claims were required. A case in point is *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356 (1822), in which the Supreme Court affirmed the circuit court's decision that the plaintiff's patent was "deficient," and that the plaintiff could not recover for infringement thereunder. The patent laws then in effect, namely the Patent Act of 1793, did not require claims, but did require, in its 3d section, that the patent applicant "deliver a written description of his invention, and of the manner of using, or process of compounding, the same, in such full, clear and exact terms, as to distinguish the same from all things before known, and to enable any person skilled in the art or science of which it is a branch, or with which it is most nearly connected, to make, compound and use the same. . . ." *Id.* at 430. In view of this language, the Court concluded that the specification of a patent had two objects, the first of which was "to enable artizans to make and use [the invention]. . . ." *Id.* at 433. The second object of the specification was

> to put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented. It is, therefore, for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practising upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

Id. at 434.

A second, policy-based rationale for the inclusion in §112 of both the first paragraph "written description" and the second paragraph "definiteness" requirements was set forth in *Rengo Co. v. Molins Mach. Co.*, 657 F.2d 535, 551, 211 USPQ 303, 321 (3d Cir.), *cert. denied*, 454 U.S. 1055 (1981):

> [T]here is a subtle relationship between the policies underlying the description and definiteness requirements, as the two standards, while complementary, approach a similar problem from different directions. Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation. The definiteness requirement shapes the future conduct of persons other than the inventor, by insisting that they receive notice of the scope of the patented device.

With respect to the first paragraph of §112 the severability of its "written description" provision from its enablement ("make and use") provision was recognized by this court's predecessor, the Court of Customs and Patent Appeals, as early as *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967). Although the appellants in that case had presumed that the rejection appealed from was based on the enablement requirement of §112, *id.* at 995, 154 USPQ at 123, the court disagreed:

> [T]he question is not whether [one skilled in the art] would be so enabled but whether the specification discloses the compound to him, specifically, *as something appellants actually invented*. . . . If [the rejection is] based on section 112, it is on the requirement thereof that "The specification shall contain a written description *of the invention* * * *." (Emphasis ours.)

Id. at 995-96, 154 USPQ at 123 (first emphasis added). The issue, as the court saw it, was one of fact: "Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound [claimed]?" *Id.* at 996, 154 USPQ at 123.

In a 1971 case again involving chemical subject matter, the court expressly stated that "it is possible for a specification to *enable* the practice of an invention as broadly as it is claimed, and still not *describe* that invention." *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971) (emphasis added). As an example, the court posited the situation "where the specification discusses *only* compound A and contains *no* broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C, yet the class consisting of A, B and C has not been described." *Id.* at 1405 n.1, 168 USPQ 593 n.1 (emphases in original). *See also In re Ahlbrecht*, 435 F.2d 908, 911, 168 USPQ 293, 296 (CCPA 1971) (although disclosure of parent application may have *enabled* production of claimed esters having 2-12 methylene groups, it only *described* esters having 3-12 methylene groups).

The CCPA also recognized a subtle distinction between a written description adequate to *support* a claim under §112 and a written description sufficient to *anticipate* its subject matter under §102(b). The difference between "claim-supporting disclosures" and "claim-anticipating disclosures" was dispositive in *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971), where the court held that a U.S. "grandparent" application did not sufficiently describe the later-claimed invention, but that the appellant's intervening British application, a counterpart to the U.S. application, anticipated the claimed subject matter. As the court pointed out, "the description of a single embodiment of broadly claimed subject matter constitutes a description of the invention for anticipation purposes . . ., whereas the same information in a specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure. . . ." *Id.* at 970, 169 USPQ at 797 (citations omitted).

The purpose and applicability of the "written description" requirement were addressed in *In re Smith and Hubin*, 481 F.2d 910, 178 USPQ 620 (CCPA 1973), where the court stated:

> Satisfaction of the description requirement insures that subject matter presented in the form of a claim subsequent to the filing date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention can fairly be held to be the filing date of the application. This concept applies whether

[3] For additional background, *see* Rollins, "35 USC 120 — The Description Requirement," 64 *J. Pat. Off. Soc'y* 656 (1982); Walterscheid, "Insufficient Disclosure Rejections (Part III)," 62 *J. Pat. Off. Soc'y* 261 (1980).

the case factually arises out of an assertion of entitlement to the filing date of a previously filed application under §120 or arises in the interference context wherein the issue is support for a count in the specification of one or more of the parties or arises in an ex parte case involving a single application, but where the claim at issue was filed subsequent to the filing of the application. *Id.* at 914, 178 USPQ at 623-24 (citations omitted).

The CCPA's "written description" cases often stressed the fact-specificity of the issue. *See, e.g., In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976) ("The primary consideration is *factual* and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure") (emphasis in original); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ("Precisely how close the description must come to comply with §112 must be left to case-by-case development"); *DiLeone*, 438 F.2d at 1405, 168 USPQ at 593 ("What is needed to meet the description requirement will necessarily vary depending on the nature of the invention claimed"). The court even went so far as to state:

> [I]t should be readily apparent from recent decisions of this court involving the question of compliance with the description requirement of §112 that each case must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited.

In re Driscoll, 562 F.2d 1245, 1250, 195 USPQ 434, 438 (CCPA 1977).

Since its inception, the Court of Appeals for the Federal Circuit has frequently addressed the "written description" requirement of §112.[6] A fairly uniform standard for determining compliance with the "written description" requirement has been maintained throughout: "Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (citations omitted). "[T]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'" *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Our cases also provide that compliance with the "written description" requirement of §112 is a question of fact, to be reviewed under the clearly erroneous standard. *Gosteli*, 872 F.2d at 1012, 10 USPQ2d at 1618; *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988).

There appears to be some confusion in our decisions concerning the extent to which the "written description" requirement is separate and distinct from the enablement requirement. For example, in *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 1209 (1985), we flatly stated: "The description requirement is found in 35 U.S.C. §112 and is separate from the enablement requirement of that provision." However, in a later case we said, "The purpose of the [written] description requirement [of section 112, first paragraph] is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined." *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1421, 5 USPQ2d 1194, 1197 (Fed. Cir. 1987), *cert. denied*, 486 U.S. 1008 (1988). "The written description must communicate that which is needed to enable the skilled artisan to make and use the claimed invention." *Id.*

[2] To the extent that *Kennecott* conflicts with *Wilder*, we note that decisions of a three-judge panel of this court cannot overturn prior precedential decisions. *See UMC Elec. Co. v. United States*, 816 F.2d 647, 652 n.6, 2 USPQ2d 1465, 1468 n.7 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988). This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

The District Court's Analysis

We agree with the district court's conclusion that drawings alone *may* be sufficient to provide the "written description of the invention" required by §112, first paragraph. Several earlier cases, though not specifically framing the issue in terms of compliance with the "written description" requirement, support this conclusion.

For example, we previously stated that "[t]here is no statutory prohibition against an applicant's reliance, in claiming priority under 35 U.S.C. §120, on a disclosure in a design application if the statutory conditions are met." *KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1574, 228 USPQ 32, 33 (Fed. Cir. 1985). The question whether the applicant's claim to a pocket for athletic shoes was in fact entitled to the filing date of his earlier design application was not resolved in *KangaROOS*, however. Issues of intent to deceive the PTO were involved, as well as an error of law by the district court in construing the claims of the wrong application. *Id.* at 1574-75, 228 USPQ at 34-35. The district court's grant of partial summary judgment of inequitable conduct was vacated and the case remanded for trial.

In re Berkman, 642 F.2d 427, 209 USPQ 45 (CCPA 1981) involved a claim under 35 USC 120 to the benefit of the filing date of two earlier design patent applications that included drawings of a carrying and storage case for tape cartridges and cassettes. The invention claimed in the later-filed utility application was an "insert" of "compartmented form," adapted for use in the interior of the storage case. *Id.* at 429, 209 USPQ at 47. The court characterized the dispositive issue as "whether the design applications sufficiently disclose the invention now claimed in the . . . utility application at bar." *Id.* at 429, 209 USPQ at 46. While specifically recognizing that "drawings may be used to satisfy the disclosure requirement," *id.* at 429, 209 USPQ at 46-47, the court held that Berkman's design applications "fail[ed] to disclose the claimed invention sufficiently to comply with the requirements of §112 first paragraph." As the court explained:

> Nowhere in the design applications is the word "insert" used, nor is there any indication that the interiors of the cases are inserts. The drawings do not disclose how the insert can be used to accommodate either cassette or cartridge type tape enclosures. Berkman argues that one skilled in the art would readily recognize that the interiors of the cases illustrated in the design drawings are inserts. We do not agree. There is nothing shown in the drawings to lead one of ordinary skill to such a conclusion.

Id. at 430, 209 USPQ at 47.

The issue in *In re Wolfensperger*, 302 F.2d 950, 133 USPQ 537 (CCPA 1962) was whether the specification of the applicant's utility patent application disclosing a ball valve, and particularly the drawings thereof, supported a claim limitation that read: "having, in untensioned condition, a mean diameter corresponding approximately to the mean diameter of said chamber and a radial width smaller than the radial width of said chamber. . . ." *Id.* at 952, 133 USPQ at 538. The court did not agree with the Board's conclusion that the "radial width" relationship was not supported by applicant's figure 5:

> The board's statement that "drawings alone cannot form the basis of a valid claim" is too broad a generalization to be valid and is, furthermore, contrary to well-

[6] *See, Chester v. Miller*, 906 F.2d 1574, 15 USPQ2d 1333 (Fed. Cir. 1990) (parent application's disclosure of chemical species constituted 102(b) prior art against continuation-in-part (c-i-p) application on appeal, but did not provide sufficient written description to support c-i-p's claims to encompassing genus); *In re Gostelli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (foreign priority application's disclosure of chemical subgenus was insufficient written description to support genus claims of corresponding U.S. application); *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989) (application in "clear compliance" with §112 "written description" requirement with respect to claim limitation that microcapsules were "not permanently fixed"); *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988) (holding generic interference count to scroll compressor supported by written description of foreign priority application, the court stated, "A specification may, within the meaning of 35 U.S.C. §112 ¶1, contain a written description of a broadly claimed invention without describing all species that claim encompasses"); *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 5 USPQ2d 1194 a (Fed. Cir. 1987) (parent application's lack of express disclosure of inherent "equiaxed microstructure" property did not deprive c-i-p's claims to a sintered ceramic body having said property of the benefit of parent's filing date), *cert. denied*, 486 U.S. 1008 (1988); *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 227 USPQ 177 (Fed. Cir. 1985) (parent application's disclosure provided adequate written description support for certain claim limitations respecting protein content, temperature, and moisture content, but not others); *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984) (broadly worded title, general description of drawing, and objects of invention of parent patent application did not adequately support reissue application claims directed to genus of indicating mechanisms for dictating machines), *cert. denied*, 469 U.S. 1209 (1985); *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983) (claims to method of redeeming merchandise coupons, comprising step of providing an audit of coupon traffic, were not supported by specification of parent application).

well-settled and long-established Patent Office practice. Consider, for one thing, that the sole disclosure in a design patent application is by means of a drawing. For another thing, consider that the only informative and significant disclosure in many electrical and chemical patents is by means of circuit diagrams or graphic formulae, constituting "drawings" in the case. The practical, legitimate enquiry in each case of this kind is what the drawing in fact discloses to one skilled in the art. The issue here is whether there is supporting "disclosure" and it does not seem, under established procedure of long standing, approved by this court, to be of any legal significance whether the disclosure is found in the specification or in the drawings so long as it is there.

Id. at 955-56, 133 USPQ at 541-42.

Employing a "new matter" analysis, the court in *In re Heinle*, 342 F.2d 1001, 145 USPQ 131 (CCPA 1965) reversed a PTO rejection of the applicant's claims to a "toilet paper core" as "including subject matter having no clear basis in the application as filed." *Id.* at 1003, 145 USPQ at 133. The claim limitation said to be without support required that the width of the apertures in the core be "approximately one-fourth of the circumference of said core." *Id.* at 1007, 145 USPQ at 136. Having reviewed the application drawings relied upon for support, the court stated:

> it seems to us that [the drawings] conform to the one-fourth circumference limitation almost exactly. But the claim requires only an approximation. Since we believe an amendment to the specification to state that one-fourth of the circumference is the aperture width would not violate the rule against "new matter," we feel that supporting disclosure exists. The rejection is therefore in error.

Id.

[3] These cases support our holding that, under proper circumstances, drawings alone may provide a "written description" of an invention as required by §112. Whether the drawings are those of a design application or a utility application is not determinative, although in most cases the latter are much more detailed. In the instant case, however, the design drawings are substantially identical to the utility application drawings.

Although we join with the district court in concluding that drawings may suffice to satisfy the "written description" requirement of §112, we can not agree with the legal standard that the court imposed for "written description" compliance, nor with the court's conclusion that no genuine issues of material fact were in dispute.

With respect to the former, the district court stated that although the '081 design drawings in question "allowed practice" [i.e., enabled], they did not necessarily show what the invention is, when "the invention" could be a subset or a superset of the features shown. Is the invention the semi-circular lumens? The conical tip? The ratio at which the tip tapers? The shape, size, and placement of the inlets and outlets? You can measure all of these things from the diagrams in serial '081 and so can practice the device, but you cannot tell, because serial '081 does not say, what combination of these things is "the invention", and what range of variation is allowed without exceeding the scope of the claims. To show one example of an invention, even a working model, is not to describe what is novel or important. 745 F.Supp. at 522, 17 USPQ2d at 1356.

[4] We find the district court's concern with "what the invention is" misplaced, and its requirement that the '081 drawings "describe what is novel or important" legal error. There is "no legally recognizable or protected 'essential' element, 'gist' or 'heart' of the invention in a combination patent." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 [128 USPQ 354] (1961). "The invention" is defined by the claims on appeal. The instant claims do not recite *only* a pair of semi-circular lumens, or a conical tip, or a ratio at which the tip tapers, or the shape, size, and placement of the inlets and outlets; they claim *a double lumen catheter* having a *combination* of those features. That combination invention *is* what the '081 drawings show. As the district court itself recognized, "what Mahurkar eventually patented is exactly what the pictures in serial '081 show." 745 F.Supp. at 523, 17 USPQ2d at 1357.

We find the "range of variation" question, much emphasized by the parties, more troublesome. The district court stated that "although Mahurkar's patents use the same diagrams, [the claims] contain limitations that did not follow ineluctably [i.e., inevitably] from the diagrams." *Id.* at 524, 17 USPQ2d at 1357. As an example, the court stated (presumably with respect to independent claims 1 and 7 of the '329 patent) that

> the utility patents claim a return lumen that is "substantially greater than one-half but substantially less than a full diameter" after it makes the transition from semi-circular to circular cross-section, and the drawings of serial '081 fall in this range. But until the utility application was filed, nothing established that they had to — for that matter that the utility patent would claim anything other than the *precise* ratio in the diagrams.

Id. at 523, 17 USPQ2d at 1357. Mahurkar argues that one of ordinary skill in this art, looking at the '081 drawings, would be able to derive the claimed range.

The declaration of Dr. Stephen Ash, submitted by Mahurkar, is directed to these concerns. Dr. Ash, a physician specializing in nephrology (the study of the kidney and its diseases) and chairman of a corporation that develops and manufactures biomedical devices including catheters, explains why one of skill in the art of catheter design and manufacture, studying the drawings of the '081 application in early 1982, would have understood from them that the return lumen must have a diameter within the range recited by independent claims 1 and 7 of the '329 patent. Dr. Ash explains in detail that a return (longer) lumen of diameter less than half that of the two lumens combined would produce too great a pressure increase, while a return lumen of diameter equal or larger than that of the two lumens combined would result in too great a pressure drop.[7] "Ordinary experience with the flow of blood in catheters would lead directly away from any such arrangement," Ash states.

Although the district court found this reasoning "logical," it noted that later patents issued to Mahurkar disclose diameter ratios closer to 1.0 (U.S. Patent No. 4,584,968) and exactly 0.5 (U.S. Des. Patent No. 272,651). If these other ratios were desirable, the district court queried, "how does serial '081 necessarily exclude the[m]?" 745 F.Supp. at 523, 17 USPQ2d at 1357.

[5] The district court erred in taking Mahurkar's other patents into account. Mahurkar's *later* patenting of inventions involving different range limitations is irrelevant to the issue at hand. Application sufficiency under §112, first paragraph, must be judged as of the filing date. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed. Cir. 1989).

[6] The court further erred in applying a legal standard that essentially required the drawings of the '081 design application to *necessarily exclude* all diameters other than those within the claimed range. We question whether any drawing could ever do so. At least with respect to independent claims 1 and 7 of the '329 patent and claims depending therefrom, the proper test is whether the drawings conveyed with reasonable clarity to those of ordinary skill that Mahurkar had in fact invented the catheter recited in those claims, having (among several other limitations) a return lumen diameter substantially less than 1.0 but substantially greater than 0.5 times the diameter of the combined lumens. Consideration of what the drawings conveyed to persons of ordinary skill is essential. *See Ralston Purina*, 772 F.2d at 1575, 227 USPQ at 179 (ranges found in applicant's claims need not correspond *exactly* to those disclosed in parent application; issue is whether one skilled in the art could derive the claimed ranges from parent's disclosure).

Mahurkar submitted the declaration of Dr. Ash on this point; Vas-Cath submitted no technical evidence to refute Ash's conclusions. Although the district court considered Dr. Ash's declaration, we believe its import was improperly disregarded when viewed through the court's erroneous interpretation of the law.[8] We hold that the Ash declaration and Vas-Cath's non-refutation thereof, without more, gave rise to a genuine issue of material fact inappropriate for summary disposition. *See Hesston Corp. v. Sloop*, 1988 U.S. Dist. LEXIS 1573, *13 (D. Kansas) (summary judgment on §112 "written description" issue inappropriate where resolution of what parent disclosure conveyed to those skilled in the art may require examination of experts, demonstrations and exhibits).

[7] Higher pressure drops are associated with smaller cross-sectional areas for fluid flow. Mahurkar's opening brief to this court states that by applying well-known principles of fluid mechanics (i.e., the work of Poiseuille and Hagen), it can be calculated that the diameter of the circular (return) lumen would have to be in the range of 0.66 times the diameter of the two lumens combined in order to achieve proper blood flow at equal pressure drop. The 0.66 ratio falls within the noted claim limitation.

[8] The following colloquy at oral argument before the district court supports our view:

Counsel for Mahurkar: "So the only evidence that we have on this subject from people of ordinary skill in the art is that the drawings do communicate these range limitations, and given the procedural posture of this case, the Court has to accept that evidence. . . ."

District Court: * * * "And if you could have written a large number of things that were different from what was actually filed in 1984, then the diagram isn't enough.

And that seems to me something that can't be resolved by ogling the Ash declaration. It's really a pure question of law."

Mahurkar urges that at least some of the remaining claims do not contain the range limitations discussed by the district court, and that the presence of range limitations was not a proper basis for invalidating those remaining claims. For example, claim 8 of the '141 patent requires, inter alia, a smooth conical tapered tip and "the portion of said tube between said second opening and said conical tapered tip *being larger than* said first lumen in the transverse direction normal to the plane of said septum." Vas-Vath counters that claim 8 of the '141 patent is just as much a "range" claim as claims 1 and 7 of the '329 patent, albeit one having only a lower limit and no upper limit.

Absent any separate discussion of these remaining claims in the district court's opinion, we assume that the court applied to them the same erroneous legal standard. Summary judgment was therefore inappropriate as to the remaining claims. Additionally, the possibility that the '081 drawings may provide an adequate §112 "written description" of the subject matter of some of the claims but not others should have been considered. *See, e.g., In re Borkowski*, 422 F.2d 904, 909 n.4, 164 USPQ 642, 646 n.4 (CCPA 1970) (on review of §112 non-enablement rejection: "A disclosure may, of course, be insufficient to support one claim but sufficient to support another.") On remand, the district court should *separately* analyze whether the "written description" requirement has been met as to the subject matter of *each* claim of the '141 and '329 patents.

CONCLUSION

The district court's grant of summary judgment, holding all claims of the '329 and '141 patents invalid under 35 USC 102(b), is hereby reversed as to all claims, and the case remanded for further proceedings consistent herewith.

COSTS

Each party to bear its own costs.

REVERSED and *REMANDED*

APPENDIX

Independent Claims of the '329 Patent:

1. A double lumen catheter having an elongated tube with a proximal first cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal end of said first cylindrical portion, wherein the improvement comprises:

said elongated tube having at its distal end a smooth conical tapered tip that smoothly merges with a second cylindrical portion of said elongated tube, and said second cylindrical portion enclosing the first lumen from the conical tapered tip to approximately the location of said second opening, wherein said second cylindrical portion has a diameter substantially greater than one-half but substantially less than a full diameter of said first cylindrical portion.

7. A double lumen catheter having an elongated tube with a proximal first cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal end of said first cylindrical portion, wherein the improvement comprises:

said elongated tube having at its distal end a smooth conical tapered tip that smoothly merges with a second cylindrical portion of said elongated tube, and said second cylindrical portion enclosing the first lumen from the conical tapered tip to approximately the location of said second opening, said second cylindrical portion having a diameter substantially greater than one-half but substantially less than a full diameter of said first cylindrical portion, said divider in said first cylindrical portion being planar, the lumens being "D" shaped in cross-section in said first cylindrical portion, the elongated tube being provided with a plurality of holes in the region of the conical tapered tip, and said first cylindrical portion of the elongated tube smoothly merging with said second cylindrical portion of the elongated tube.

Independent Claims of the '141 Patent:

1. A double lumen catheter having an elongated tube with a proximal first cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal end of said first cylindrical portion, wherein the improvement comprises:

said elongated tube having at its distal end a smooth conical tapered tip that smoothly merges with a second cylindrical portion of said elongated tube, and said second cylindrical portion enclosing the first lumen from the conical tapered tip to approximately the location of said second opening, wherein said second sylindrical [sic] portion has a diameter substantially less than a full diameter of said first cylindrical portion but larger than said first lumen in the transverse direction normal to the plane of said flat divider.

7. A double lumen catheter comprising an elongated cylindrical tube enclosing first and second lumens separated by a flat longitudinal internal divider formed as an integral part of said tube, said tube and said divider forming said first and second lumens as semi-cylindrical cavities within said tube, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, said distal end of said tube forming a smooth conical tapered tip and the second lumen extending from the proximal end of said elongated tube to a second opening spaced a substantial distance away from said first opening toward the proximal end of said tube, the distal end of said divider being joined to the outside wall of said tube distal of said second opening, and the outside wall of said tube forming a smooth transition between said conical tapered tip and the outer circumference of the tube proximal of said second opening, said transition being larger than said first lumen in the transverse direction normal to the plane of said flat divider.

8. A double lumen catheter comprising an elongated cylindrical tube having a longitudinal planar septum of one-piece construction with said tube, said septum dividing the interior of said tube into first and second lumens, said lumens being D-shaped in cross-section, the proximal end of said tube connecting to two separate tubes communicating with the respective first and second lumens for the injection and removal of fluids, the lumen extending from the proximal end of said tube to a first lumen extending from the proximal end of said tube to a first opening at the distal end of said tube, and the second lumen extending from the proximal end of said tube to a second opening axially spaced from the distal end of said tube, said tube having at its distal end a smooth conical tapered tip that merges with the cylindrical surface of said tube, said first lumen, including the internal wall thereof formed by said septum extending continuously through said conical tapered tip, and the portion of said tube between said second opening and said conical tapered tip being larger than said first lumen in the transverse direction normal to the plane of said septum.

13. A double lumen catheter comprising an elongated cylindrical tube enclosing first and second lumens separated by a flat longitudinal internal divider formed as an integral part of said tube, said tube and said divider forming said first and second lumens as semi-cylindrical cavities within said tube, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with he [sic] respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, said distal end of said tube forming a smooth conical tapered tip defining the distal portion of said first lumen and said first opening, said first opening and an adjacent portion of said first lumen having a circular transverse cross-sectional configuration, and the second lumen extending from the proximal end of said elongated tube to a second opening spaced a substantial distance away from said first opening toward the proximal end of said tube, the inside walls of said tube forming a smooth transition between said semicylindrical and circular transverse cross-sectional configurations of said first lumen, the outside dimension of said transition being larger than said first lumen in the transverse direction normal to the plane of said flat divider.

District Court, N.D. Illinois

Spraying Systems Co. v. Delavan Inc.

No. 89 C 8447

APPENDIX 'B'

years' worth of license fees, or $1,260, since the date of its first letter to defendants on September 23, 1933 informing them that they were required to sign a license agreement. By imposing the statutory minimum of $500 per number of works infringed,[3] defendants will be required to pay $11,500, approximately nine times the amount defendants would have paid in licensing fees. This Court finds that to be an appropriate penalty for the defendants' infringements.

Finally, the Copyright Act provides that the court "in its discretion may allow the recovery of full costs [and] may also award a reasonable attorney's fee to the prevailing party as part of the costs." 17 U.S.C. § 505. In order to encourage suits to redress copyright infringement, attorney fees are awarded to a prevailing plaintiff as a matter of course. *Frost Belt Int'l Recording Enterprises, Inc. v. Cold Chillin' Records*, 758 F.Supp. 131, 140 (S.D.N.Y. 1990). The award of attorney's fees is the rule rather than the exception. *Micromanipulator Co. v. Bough*, 779 F.2d 255, 259 [228 USPQ 443] (5th Cir. 1985). Consequently, this Court finds plaintiffs entitled to reasonable attorney's fees for the prosecution of this action.

The declaration of Marjorie R. Esman submitted by plaintiffs states that plaintiffs incurred $1,747.00 in attorney's fees for services, including: preparation and service of discovery materials, participation in a scheduling conference; preparation of and filing of a witness and exhibit list; preparation and filing of the motion for summary judgment. The declaration states that plaintiffs incurred costs and expenses in the amount of $485.37 for filing of the complaint, payments to the process server, reasonable photocopies, and long distance telephone charges. This Court finds these declared attorneys's fees, costs and expenses to be reasonable.

Conclusion

For the reasons set forth above,

IT IS ORDERED that plaintiffs' motion for summary judgment is hereby GRANTED in all respects except plaintiffs' request for statutory damages in the amount of $2,500 per claim of infringement. Accordingly, defendants are liable to plaintiffs in the amount of $11,500 in statutory damages for copyright infringements, $1,747.00 in attorney's fees, and $485.37 in costs and expenses. Judgment will be so entered.

[3] See *Frank Music Corp. v. Metro-Goldwyn-Mayer Inc.*, (9th Cir.), 886 F.2d 1545 [12 USPQ2d 1412], *cert. den'd* 110 S.Ct. 1321, 494 U.S. 1017 (1989) which states that the number of works infringed is the appropriate calculation for statutory damages and not the number of infringements. The affidavit of James Hutcherson, investigator for BMI, lists 23 works which were infringed on July 11, 12, 18, and 19, 1992.

U.S. Patent and Trademark Office
Board of Patent Appeals and Interferences

Ex parte Parks

No. 93-2740

Decided September 2, 1993
Released January 4, 1994

PATENTS

1. Practice and procedure in Patent and Trademark Office — Reissue — Broader claims sought (§110.1313)

Patentability/Validity — Specification — Written description (§115.1103)

Claims in reissue application for method of determining nitrogen content of sample were improperly rejected on ground of inadequate descriptive support under 35 USC 112, first paragraph, since originally-filed disclosure need only convey, to one of skill in art, that applicant had possession of concept of what is claimed in order to satisfy description requirement, since lack of literal basis in disclosure for limitation that decomposition step of claims be "conducted in the absence of a catalyst" thus does not establish prima facie case for lack of descriptive support, and since it cannot be held that originally-filed disclosure would not have conveyed concept of effecting decomposition at elevated temperature in absence of catalyst.

2. Practice and procedure in Patent and Trademark Office — Reissue — Broader claims sought (§110.1313)

Claims in reissue application for method of determining nitrogen content of sample are overbroad under 35 USC 251, since application was filed more than two years after grant of original patent, since any claim which does not contain negative limitation expressly excluding presence of catalyst in decomposition step of method is broader than original claims, and since claims in question do not accomplish such exclusion by reciting phrase "consisting essentially of" in characterizing decomposition step.

Particular patents — Chemical — Nitrogen detection

4,018,562, Parks and Marietta, chemiluminescent nitrogen detection apparatus and method, claims 81-93 in application for reissue rejected.

Appeal from final rejection of claims in application for reissue of patent (Jill Johnston, primary examiner).

Application of Robert E. Parks and Robert L. Marietta, serial no. 708,810, filed May 31, 1991, continuation of serial no. 340,540, filed April 18, 1989 and abandoned, for reissue of patent no. 4,018,562, granted April 19, 1977 on application serial no. 625,510, filed Oct. 24, 1975 (chemiluminescent nitrogen detection apparatus and method). From final rejection of all claims in application, applicants appeal. Rejection of claims 1-10, 20-22, 55-80, and 94-106 reversed; rejection of claims 81-93 affirmed.

Before Calvert, vice chairman, and Steiner and Tarring, examiners-in-chief.

Steiner, examiner-in-chief.

This is an appeal from the final rejection of claims 1 through 10, 20 through 22 and 55 through 106, all the claims in this application for reissue of Patent No. 4,018,562 (the '562 patent).

THE INVENTION

The claimed invention is a method for determining the nitrogen content of a sample comprising manipulative steps which include decomposing the sample in an oxygen/inert gas atmosphere at an elevated temperature to obtain nitric oxide and causing the generated nitric acid to undergo a chemiluminescent reaction with ozone.

Claims 1, 81 and 94 are illustrative and read as follows:

1. The method for determining the total chemically combined nitrogen content of a sample comprising the steps:

a. decomposing said sample in one step in the presence of an oxygen-rich atmosphere of oxygen and an inert gas and at a temperature sufficiently above 700°C. that substantially all of the chemically bound nitrogen is recovered as nitric oxide (NO), such decomposition being conducted in the absence of a catalyst,

b. causing the nitric oxide produced by such decomposition to undergo a chemiluminescent reaction with ozone, and

c. determining the magnitude of the chemiluminescent reaction to indicate the quantity of chemically combined nitrogen in said sample.

81. A method for determining the total chemically combined nitrogen content of a sample, said method comprising the steps of:

(a) decomposing said sample in one step, said decomposing step consisting essentially of decomposing said sample in the presence of an oxygen-rich atmosphere of oxygen and an inert gas and at a temperature sufficiently above 700°C that substantially all of the chemically bound nitrogen is recovered as nitric acid (NO);

(b) causing the nitric oxide produced by such decomposition to undergo a chemiluminescent reaction with ozone; and

(c) determining the magnitude of the chemiluminescent reaction to indicate the quantity of chemically combined nitrogen in said sample.

94. A method for determining the total chemically combined nitrogen content of a sample, said method comprising the steps of:

(a) decomposing said sample in one step in the presence of an oxygen-rich atmosphere of oxygen and an inert gas and at a temperature sufficiently above 700°C that substantially all of the chemically bound nitrogen is recovered as nitric oxide (NO) according to the formula:

$$R\text{-}N+O_2 \triangleright CO_2+H_2O+NO$$

(b) causing the nitric oxide produced by such decomposition to undergo a chemiluminescent reaction with ozone; and

(c) determining the magnitude of the chemiluminescent reaction to indicate the quantity of chemically combined nitrogen in said sample.

THE REJECTIONS

Claims 1 through 10, 20 through 22 and 55 through 80 stand rejected under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support. Claims 81 through 106 stand rejected under 35 U.S.C. 251 in that they are broader than the originally patented claims.[1] In addition, all the

[1] The ultimate paragraph of 35 U.S.C. 251 reads as follows:

No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

appealed claims stand rejected under 35 U.S.C. 251 for lack of the requisite "error."

The rejection under the first paragraph of 35 U.S.C. 112, the rejection of claims 94 through 106 under 35 U.S.C. 251 as broader than the original claims, and the rejection of all the appealed claims under 35 U.S.C. 251 for lack of the requisite "error" are reversed; the rejection of claims 81 through 93 under 35 U.S.C. 251 as broader than the original claims is affirmed.

OPINION

The Rejection of Claims 1 through 10, 20 through 22, and 55 through 80 under the first paragraph of 35 U.S.C. 112.

The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention on any ground is always upon the examiner. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In rejecting a claim under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support, it is incumbent upon the examiner to establish that the originally-filed disclosure would not have reasonably conveyed to one having ordinary skill in the art that an appellant had possession of the now claimed subject matter. *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993). Adequate description under the first paragraph of 35 U.S.C. 112 does not require *literal* support for the claimed invention. *In re Herschler*, 591 F.2d 693, 200 USPQ 711 (CCPA 1979); *In re Edwards*, 568 F.2d 1349, 196 USPQ 465 (CCPA 1978; *In re Werthein*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed. *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973).

[1] The examiner contends that the rejected claims lack adequate descriptive support because there is "no literal basis for the"[2] claim limitation "in the absence of a catalyst." Clearly, the observation of a lack of literal support does not, in and of itself, establish a *prima facie* case for lack of adequate descriptive support under the first paragraph of 35 U.S.C. 112. *In re Herschler, supra; In re Edwards, supra; In re Wertheim, supra.*

The examiner notes that in *Parks v. Fine*, 773 F.2d 1577, 227 USPQ 432 (Fed. Cir. 1985), involving the claimed subject matter, the limitation "in the absence of a catalyst" was considered material. Suffice it to say, no issue under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support for the limitation "in the absence of a catalyst" was before the court.

We are not unmindful of the decision in *Ex parte Grasselli*, 231 USPQ 393 (Bd.App. 1983) *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984), which involved claims to a process for the ammoxidation of propane or isobutane employing a catalyst "free of uranium and the combination of vanadium and phosphorus." Under the particular facts in that case, it was held that the negative limitation introduced new concepts in violation of the description requirement of the first paragraph of 35 U.S.C. 112, citing *In re Anderson, supra.* In the situation before us,[3] it cannot be said that the originally-filed disclosure would not have conveyed to one having ordinary skill in the art that appellants had possession of the *concept* of conducting the decomposition step generating nitric acid in the absence of a catalyst. See, for example, column 5 of the '562 patent, first paragraph, wherein FIG. 4 is discussed. Pyrolysis temperatures of between 600°C and 700°C, and above 700°C were employed to achieve conversion of chemically bound nitrogen to nitric oxide. Smooth conversion was obtained above 700°C, while the optimum conversion was found to occur above 900°C. Throughout the discussion which would seem to cry out for a catalyst if one were used, no mention is made of a catalyst.[4]

Moreover, according to two declarations by Wentworth, a professor of chemistry at the University of Houston, whose expertise in this particular art has not been challenged, one having ordinary skill in the art would have recognized that the reaction generating nitric oxide, according to the equation disclosed in the '562 patent, is conducted without a catalyst. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Lemin*, 364 F.2d 864, 150 USPQ 546 (CCPA 1966). Thus, it cannot be said that the originally-filed disclosure would not have conveyed to one having ordinary skill in the art the concept of effecting decomposition at an elevated temperature in the absence of a catalyst. *In re Anderson, supra.*

Accordingly, the examiner's rejection of claims 1 through 10, 20 through 22 and 55 through 80 under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support is reversed.

The Rejection of Claims 81 through 106 under 35 U.S.C. 251 as Broader than the Original Claims.

We initially observe that on page 6 of the Brief,

> appellants agree that any claim in the reissue application that does not contain a limitation that *means* "in the absence of a catalyst" is broader than original claims 1-10 and hence unpatentable under 35 USC 251 (appellants' emphasis).

Claims 81 through 106 do not contain a negative limitation which expressly precludes the presence of a catalyst. However, appellants contend that claims 81 through 93 exclude the presence of a catalyst by virtue of the phrase "consisting essentially of" in characterizing the decomposition step, and that claims 94 through 106 exclude the presence of a catalyst by virtue of the recited equation for the decomposition reaction, which equation does not reflect the presence of a catalyst.

[2] In our opinion, the phrase "consisting essentially of," as employed in claims 81 through 93, limits decomposition to a single step and, in that sense, is redundant since decomposition is performed "in one step." However, it is not apparent and appellants have not explained why the expression "consisting essentially of" excludes the presence of a catalyst during the recited decomposition step.[5] It would, therefore, appear that claims 81 through 93 are broader than original claims 1 through 10 and, hence, were properly rejected by the examiner under 35 U.S.C. 251. Accordingly, the examiner's rejection of claims 81 through 93 under 35 U.S.C. 251 is affirmed.

Claims 94 through 106 recite the decomposition reaction in a manner which, according to the Wentworth declarations, means that no catalyst was employed. *In re Lemin, supra.* Accordingly, claims 94 through 106 would not appear broader than original claims 1 through 10 and, hence, the examiner's rejection of claims 94 through 106 under 35 U.S.C. 251 is reversed.

The Rejection of the Appealed Claims Under 35 U.S.C. 251 for Lack of the Requisite Error.

This rejection is reversed essentially for the reasons advocated by appellants on appeal. We emphasize that the practice of submitting claims as a hedge against the possible invalidity of original claims has been judicially sanctioned. See, for example, *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 11 USPQ2d 1750 (Fed. Cir. 1989); *In re Altenpohl*, 500 F.2d 1151, 183 USPQ 38 (CCPA 1974); *In re Handel*, 312 F.2d 943, 136 USPQ 460 (CCPA 1963).

In summary, the examiner's rejection of claims 81 through 93 is affirmed; the rejection of claims 1 through 10, 20 through 22, 55 through 80 and 94 through 106 is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR 1.136(a). See the final rule notice, 54 F.R. 29548 (July 13, 1989), 1105 O.G. 5 (August 1, 1989).

AFFIRMED-IN-PART.

U.S. Patent and Trademark Office
Board of Patent Appeals and Interferences

Ex parte Heymes

No. 93-1646

Decided November 9, 1993
Released January 4, 1994

PATENTS

1. Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Patentability/Validity — Obviousness — Secondary considerations generally (§115.0907)

Application claims for chemical compounds were properly rejected as obvious under 35 USC 103, since claims are prima facie obvious in view of cited references, since record does not show that claimed compounds, which are intermediates to patented compounds having antibiotic properties, have no known utility other than as

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[2] See page 4 of the Answer, second full paragraph, line 4, and page 7 thereof, last two lines.

[3] Whether the requirement for an adequate written description has been met is a question of fact and, hence, driven by the exigencies of each case. *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993).

[4] A "catalyst" normally functions to accelerate a particular reaction. See for example, Hawley, *Condensed Chemical Dictionary*, Tenth Edition, 1981, pp. 205 and 206, copies of which are enclosed for appellants' convenience and made of record.

[5] Compare *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805, 812, note 6 (Fed. Cir. 1986).

APPENDIX 'C'

above, the case law requires SunAmerica to establish (1) that it has a protectible trademark interest in SUN LIFE OF AMERICA, and (2) that Sun Life of Canada's use of the mark SUN LIFE (U.S.) creates a likelihood of confusion with SUN LIFE OF AMERICA. With respect to the first element, SunAmerica must not only survive Sun Life of Canada's counterclaim, *see supra* slip op. at _____, but also establish the acquisition of protectible trademark rights, either because SUN LIFE OF AMERICA is inherently distinctive or because it has acquired secondary meaning. *See Investacorp*, 931 F.2d at 1522. With respect to confusion, the district court's analysis should again follow the seven-factor test as established in cases like *Dieter* and *Jellibeans* to determine whether or not Sun Life of Canada's use of SUN LIFE (U.S.) creates a likelihood of confusion with SUN LIFE OF AMERICA.

I think it also prudent to address Sun Life of Canada's "causation" argument. Sun Life of Canada argues repeatedly on this appeal that the "cause" of public confusion (if any) it not its use of SUN LIFE (U.S.), but the combination of SunAmerica's use of a mark that begins with "Sun Life" and SunAmerica's relatively recent entrance into the business of selling annuities through broker dealers. Sun Life of Canada is certainly correct in pointing out that the only reason the change in geographical designation might make a difference is that in this case, both parties have operated under names that begin with "Sun Life."

Nevertheless, historical similarities occasioned by the parties' dual use of "Sun Life" would not necessarily disqualify Sun Life of America from obtaining an injunction. Should the district court find it necessary to reach the issue of whether or not SUN LIFE (U.S.) is confusingly similar to SUN LIFE OF AMERICA, it will only be because there has been a prior finding that SunAmerica has a protectible trademark interest in SUN LIFE OF AMERICA and that Sun Life of Canada has acquiesced to that interest. At such a point, SunAmeria's mark and Sun Life of Canada's mark would stand in parity. Under these circumstances, even if Sun Life of America then took advantage of industry trends by shifting to the sale of annuities through broker-dealers, it would be entitled to assume that no party would take further steps that would generate a greater likelihood of confusion than that which previously existed at the time of acquiescence. Therefore, if SunAmerica has enforceable rights in SUN LIFE OF AMERICA, it is not fatal to SunAmerica's claim that a "but-for" cause of public confusion might be SunAmerica's expansion into annuity products and the broker-dealer markets, or that there may have been residual similarities stemming from the parties' respective uses of "Sun Life" for 75 years. As long as the district court finds, based upon a careful analysis of the evidence, that Sun Life of Canada's use of SUN LIFE (U.S.) now creates an *additional* likelihood of confusion, and injunction will lie.[10]

Finally, after resolving the issues raised by Sun Life of Canada's counterclaim and reaching a decision as to whether SunAmerica can establish a prima facie case under section 43(a), the district court should consider the two affirmative defenses proffered by Sun Life of Canada — laches and acquiescence. The trial court may not have understood that Sun Life of Canada's affirmative defenses focus upon a different time period than SunAmerica's apparent defense to the counterclaim. Sun Life of Canada's defenses focus not upon the long history of the two companies, but upon the relatively shorter period of time that Sun Life of Canada has been utilizing the mark SUN LIFE (U.S.).

Sun Life of Canada first argues that SunAmerica should be estopped from contesting the use of SUN LIFE (U.S.) because SunAmerica had actual knowledge of the use of SUN LIFE (U.S.) in 1982, yet waited until June 1989 to file suit, after Sun Life of Canada sold 4 billion dollars of products under the SUN LIFE (U.S.) mark. Such delay, Sun Life of Canada contends, constitutes laches. To establish this defense, Sun Life of Canada must prove:

(1) a delay in asserting a right or a claim,
(2) that the delay was not excusable, and
(3) that there was undue prejudice to the party against whom the claim is asserted.

Ambrit, Inc. v. Kraft, Inc., 812 F.2d 1531, 1545 [1 USPQ2d 1161] (11th Cir. 1986), *cert. denied*, 481 U.S. 1041, 107 S.Ct. 1983, 95 L.Ed.2d 822 (1987). Stated differently, SunAmerica is only estopped from asserting its SUN LIFE (U.S.) claim if Sun Life of Canada demonstrates that it suffered undue prejudice while SunAmerica inexcusably delayed in asserting its rights. While I express no opinion on the laches argument, I anticipate that the district court will consider all of the relevant facts and circumstances before reaching a conclusion on this equitable defense.

[10] Sun Life of Canada also contests the admissibility and authenticity of certain evidence before the district court. I express no opinion on this issue. I trust that on remand, the district court will ascertain that the evidence it considers is admissible and authentic.

Sun Life of Canada next alleges that SunAmerica should be estopped from contesting the use of SUN LIFE (U.S.) because SunAmerica implicitly acquiesced to the use of SUN Life (U.S.) by acting as an agent of Sun Life of Canada and selling Sun Life of Canada's products under the name SUN LIFE (U.S). Put another way, Sun Life of Canada contends that by selling products designated by SUN LIFE (U.S.), SunAmerica implicitly consented to Sun Life of Canada's use of that specific mark (even if potentially confusing). To establish this acquiescence defense, Sun Life of Canada would need to establish the three elements identified above: active representation, inexcusable delay, and undue prejudice. *See supra* slip op. at _____ - _____. I note for the district court that an "active representation" need not come via a "specific endorsement" or formal agreement, *see* R15-137-16; rather, implied acquiescence may be inferred from a clear encouragement of the use of the allegedly infringing mark, as when, for example, the plaintiff substantially contributes to the marketing of the allegedly infringing products. *See, e.g., Coach House*, 934 F.2d at 1563-64; *ConAgra*, 743 F.2d at 1516-18; *Land O'Lakes, Inc. v. Land O'Frost, Inc.*, 224 U.S.P.Q. 1022, 1029-30 (TTAB 1984); *Hitachi Metals Int'l v. Yamakyu Chain Kabushiki*, 209 U.S.P.Q. 1057, 1067 (TTAB 1981). Once again, in deciding this issue, the district court should carefully consider SunAmerica's proffered reasons for its alleged acquiescence and delay. *See supra* slip op. at _____ - _____.

IV.

SunAmerica has described this case as "open-and-shut" because Sun Life of Canada has allegedly used an identical mark for competitive products. *See* Appellees' Br. at 4 n.2 (citing 2 J. Thomas McCarthy, *Trademarks and Unfair Competition* § 23:3, at 56 (2d ed. 1984)). As evidenced by my discussion, I am unpersuaded as to that conclusion. This case has a complex and unique history that spans over 100 years. Both parties to this dispute have persuasive claims, counterclaims, and defenses. All are interrelated. All require not only a careful analysis of each party's trademarks, products, markets, clients, and distribution channels, but also an analysis of how circumstances may have changed over time. Arguably, in this case, convergence has created competition and confusion. Only precise, step-by-step detailed analysis can illuminate an appropriate resolution that is capable of meaningful appellate review. To suggest otherwise ignores the complexity and subtlety presented in this case.

U.S. Patent and Trademark Office
Board of Patent Appeals and Interference

Staehelin v. Secher

No. 101,597

Decided September 28, 1992
Released October 8, 1992

PATENTS

1. Practice and procedure in Patent and Trademark Office — Interference — Burden of proof (§110.1707)

Patentability/Validity — Specification — Enablement (§115.1105)

Moving party in interference proceeding ordinarily bears burden of proof; thus, party moving for judgment on grounds that opposing party's claims corresponding to count are unpatentable because opposing party's earlier filed British application does not meet requirements of 35 USC 112, first paragraph, bears burden of making out prima facie case of non-enablement.

2. Patentability/Validity — Specification — Enablement (§115.1105)

Specification, in order to satisfy enablement requirement under 35 USC 112, first paragraph, need not be "blueprint" which, if followed, would unfailingly reproduce exactly applicant's claimed invention; rather, only objective enablement without resort to undue experimentation is required, and thus party in interference which claims that disclosure is non-enabling but which has failed to present persuasive, objective evidence that, at time invention was made, undue experimentation would have been required by those skilled in art in order to practice invention, has failed to meet its burden of making out prima facie case of non-enablement.

3. Patentability/Validity — Specification — Written description (§115.1103)

Function of "written description" requirement of 35 USC 112, first paragraph, is to ensure that applicant had possession, as of filing date of application relied upon, of subject matter later claimed by applicant;

inquiry into satisfaction of written description requirement is factual, depending on nature of invention and amount of knowledge imparted by disclosure to those skilled in art.

4. Practice and procedure in Patent and Trademark Office — Interference — Pleadings and submissions (§110.1706)

Patentability/Validity — Specification — Best mode (§115.1107)

Board of Patent Appeals and Interferences will not consider assertion, by party in interference, that opposing party's disclosure failed to satisfy best mode requirement of 35 USC 112, first paragraph, since party's motion for judgment on grounds that opposing party's claims were unpatentable failed to include any argument or evidence concerning best mode, but rather such best mode arguments were raised for first time in party's brief at final hearing.

5. Patentability/Validity — Date of invention — In general (§115.0401)

Party in interference which conceived its invention in Switzerland may not rely on evidence of such conception for purposes of proving priority, but may still be awarded priority if it demonstrates, by preponderance of evidence, an introduction of conception into U.S. prior to opposing party's constructive reduction to practice, coupled with reasonable diligence from time period just prior to opposing party's entry into field up to its reduction to practice.

6. Patentability/Validity — Date of invention — Conception (§115.0403)

Evidence of conception which names only one of actual inventive entity inures to benefit of, and serves as evidence of conception by, complete inventive entity.

7. Patentability/Validity — Date of invention — Reduction to practice (§115.0405)

Receipt in U.S. of nine monoclonal antibodies, along with explanatory letter characterizing nature of monoclonal antibodies, does not constitute introduction of actual reduction of subject matter of count into U.S., without any evidence showing that compound introduced into U.S. and identified as compound within count was subjected to testing in U.S.

8. Patentability/Validity — Date of invention — Diligence (§115.0409)

Activities abroad will not be considered for purposes of establishing diligence in reducing invention to practice; inventor whose work, prior to introduction into U.S. of samples of monoclonal antibodies produced in Switzerland, was performed only in Switzerland cannot rely on such activity to establish date of invention.

Particular patents — Chemical — Monoclonal antibodies

4,423,147, Secher and Burke, monoclonal antibody to interferon-α, inventors held entitled, in interference, to patent containing claims 1 through 7.

Patent interference between application of Theophil Staehelin, Christian Stahli, and Vicenzo Miggiano, serial no. 06/612,762, filed May 22, 1984, accorded benefit of serial no. 07/351,282, filed Feb. 22, 1982, and Swiss application nos. 7773/81, filed Dec. 4, 1981, and 1343/81, filed Feb. 27, 1981, and patent granted to David S. Secher and Derek C. Burke on Dec. 27, 1983, patent no. 4,423,147, serial no. 06/333,856, filed Dec. 10, 1981, accorded benefit of U.K. application nos. 8012096, filed April 11, 1980, 035884, filed Nov. 7, 1980, and PCT application No. GB81/00067, filed April 13, 1981 (antibodies against proteins). Senior party Secher and Burke held entitled to their patent containing claims 1 through 7 corresponding to the count.

William H. Epstein, John S. Saxe, Bernard S. Leon, George M. Gould, William G. Isgro, Peter R. Shearer, and Steve T. Zelson, Nutley, N.J., and William H. Vogt, III, David R. Plautz, and Stephen M. Haracz, White Plains, N.Y., for Staehelin, et al.

Watson T. Scott, John W. Malley, Paul N. Kokulis, Allen Kirkpatrick, David E. Varner, Lloyd J. Street, George T. Mobille, James L. Dooley, Alvin Guttag, Raymond F. Lippitt, G. Lloyd Knight, Carl G. Love, Lawrence A. Hymo, Akin T. Davis, Edgar H. Martin, William K. West, Jr., Kevin E. Joyce, Edward M. Prince, Donald B. Deaver, David W. Brinkman, George M. Sirilla, William T. Bullinger, Donald J. Bird, Larry S. Nixon, James R. Longacre, Arthur R. Crawford, W. Warren Taltavull, Michael L. Keller, Charles R. Donohoe, Sherman O. Parrett, and Robert A. Vanderhye, Washington, D.C., for Secher, et al.

Before Sofocleous, Downey, and Metz, examiners-in-chief.

Metz, examiner-in-chief.

This interference involves an application of Staehelin et al. assigned to Hoffman-LaRoche Inc. and a patent of Secher et al. which is unassigned according to the records of the Patent and Trademark Office.

The subject matter at issue relates to a monoclonal antibody produced by a murine derived hybrid cell line wherein the antibody is capable of specifically binding to at least one antigenic determinant of interferon-α [1]. The sole count at issue corresponds exactly to claim 1 of the Secher et al. (Secher) patent and reads as follows:

Count 1

A monoclonal antibody produced by a murine derived hybrid cell line wherein the antibody is capable of specifically binding to at least one antigenic determinant of interferon-α.

The claims of the parties which have been designated as corresponding to the count are:

Staehelin et al.	Claims 10-12, 14, 16-21 and 23-25
Secher et al.	Claims 1-7

Both parties requested a testimony period. Staehelin et al. (Staehelin) requested a rebuttal testimony period. Both parties presented testimony, affidavits and associated exhibits in support of their respective positions.[2] Both parties filed briefs. Staehelin filed a reply brief. Both parties were represented by their respective legal representatives at final hearing. No issue of interference-in-fact was raised.

The issues presented for decision by the Board of Patent Appeals and Interferences are: 1) the propriety of the Examiner-in-Chief's (EIC's) denial of Staehelin's preliminary motion for judgment on the ground that Secher's claims are unpatentable for failure to comply with 35 USC 112, paragraph 1, as lacking an adequate "written description" of the genus embraced by Secher's claims corresponding to the count and as being based on a non-enabling disclosure, in light of newly presented evidence adduced from the parties' testimony [3]; 2) the propriety of the EIC's denial of Staehelin's motion for judgment on the grounds that Secher's claims corresponding to the count are unpatentable under 35 USC 102 and 35 USC 103; 3) the propriety of the EIC's denial of Secher's preliminary motion for judgment on the grounds that Staehelin's claims corresponding to the count are unpatentable under 35 USC 102 and 35 USC 103; 4) the propriety of the EIC's granting Secher's motion for benefit of their earlier filed British applications; 5) priority of invention; and, 6) Secher's motion under 37 CFR 1.656(h) to suppress certain evidence proffered from Staehelin's testimony.

THE DECISION ON PRELIMINARY MOTIONS

In Paper Number 45, mailed on May 28, 1987, the EIC denied both of Staehelin's motions for judgment; denied Secher's motions for judgment; denied Secher's motion to deny Staehelin benefit of their earlier filed Swiss applications; dismissed without prejudice Secher's motion for judgment on the ground that Staehelin's claims are unpatentable for inequitable conduct; and, granted Secher's motion for the benefit of their earlier filed British applications. In view of the granting of Secher's motion for benefit, the order of the parties was reversed.

Staehelin requested reconsideration of the EIC's granting of Secher's motion for benefit of its earlier filed British applications in Paper Number 46 and, on June 23, 1987, a panel of this Board denied Staehelin's request for reconsideration after concluding

[1] Interferon-α is produced by leukocyte cells and is, therefore, also known as leukocyte interferon. See StaX 55, column 2, lines 21 through 23.

[2] References to the Staehelin brief will be designated by StaB, followed by the page number. References to the Staehelin reply brief will be designated by StaRB, followed by the page number. References to the Staehelin record will be designated StaR, followed by the page number. References to the Staehelin exhibits and cross exhibits will be designated by StaX and StaCX, respectively, followed by the exhibit number. References to the Secher et al. (Secher) brief will be designated SB, followed by the page number. References to the Secher record will be designated SR, followed by the page number. References to the Secher exhibits will be designated by SX, followed by the exhibit number.

[3] Ordinarily, preliminary motions should be supported by facts which would justify granting the motion, 37 CFR 1.639(a). It is not appropriate to file a motion, see if the motion will be granted, and then ask for testimony only after the motion is denied. *Hanagan v. Kimura*, 16 USPQ2d 1791 (Comm'r. 1990), *Orikasa v. Oonishi*, 10 USPQ2d 1996, n.12 (Comm'r. 1989). However, given the state of the law at the time the parties requested testimony and because the EIC granted the parties a testimony period, *in this instance*, we will consider the parties' additional evidence adduced in the testimony period.

that the EIC properly granted Staehelin's motion for benefit (Paper Number 47).

THE COUNT

It is by now well-settled that, absent ambiguity, a count in an interference is to be given the broadest, reasonable interpretation that the language of the count permits without resort to either party's disclosure. *DeGeorge v. Bernier*, 768 F.2d 1318, 226 USPQ 758 (Fed. Cir. 1985); *Fontijn v. Okamoto*, 518 F.2d 610, 186 USPQ 97 (CCPA 1975); *Lamont v. Berguer*, 7 USPQ2d 1580 (BPAI 1988). Accordingly, we construe the subject matter defined by the count in this interference as being directed to any monoclonal antibody (MAB) produced by a hybridoma derived from a mouse which MAB binds to at least one antigenic determinant of interferon-α in any amount or to any degree.

OPINION

Issues 1) and 2)

Staehelin's motions for judgment were based on the grounds that Secher's earlier filed British applications did not meet the requirements of 35 USC 112, first paragraph with respect to enablement and written description for the subject matter claimed by Secher in its later filed U.S. application, and, in part, on the grounds that certain references which were published after the filing date of Secher's earlier filed British applications, but before Secher's U.S. filing date, were "prior art" with respect to the subject matter claimed in Secher's U.S. application which "prior art" rendered the claims therein unpatentable under 35 USC 102 and 35 USC 103.

The question of whether or not references which "intervened" between the filing date of Secher's British applications whose benefit had been sought under 35 USC 119 and the filing date of Secher's later filed U.S. application depends on whether Secher's earlier filed British applications support, within the meaning of section 112, first paragraph, what is claimed in Secher's U.S. application. *In re Gostelli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Thus, the ultimate resolution of the issues delineated as 1) and 2), above, necessarily depends on whether or not Secher's earliest filed British Application No. 8012096 (British I) complies with the requirements of 35 USC 112 implicit in 35 USC 119.[4]

[4] *Kawai v. Metlesics*, 480 F.2d 880, 178 USPQ 158 (CCPA 1973).

Issue 1) — Enablement of Secher's Involved Patent Disclosure

[1] We begin by noting the fundamental precept that the moving party ordinarily bears the burden of proof. See *Weil v. Fritz*, 601 F.2d 551, 202 USPQ 447 (CCPA 1979), especially the cases cited at 601 F.2d 555, 202 USPQ 450 [1], and 37 CFR 1.637(a). Thus, Staehelin, as the party moving for judgment on the grounds that Secher's claims corresponding to the count are unpatentable because Secher's British I does not meet the requirements of 35 USC 112, first paragraph, bears the burden of making out a *prima facie* case of nonenablement. This Staehelin has failed to do.

It has been consistently held that the first paragraph of 35 USC 112 requires nothing more than objective enablement. *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). In satisfying the enablement requirement, an application need not teach, and preferably omits, that which is well-known in the art. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). How such a teaching is set forth, whether by the use of illustrative examples or by broad descriptive terminology, is of no importance since a specification which teaches how to make and use the invention in terms which correspond in scope to the claims *must* be taken as complying with the first paragraph of 35 USC 112 *unless* there is reason to doubt the objective truth of the statements relied upon therein for enabling support. *Marzocchi* at 439 F.2d 223, 169 USPQ 369.

[2] The error we see in Staehelin's approach to the question before us is that Staehelin would require a patent specification to be a blueprint which, if followed, would unfailingly reproduce exactly an applicant's claimed invention. However, the law does not require a specification to be a blueprint in order to satisfy the requirement for enablement under 35 USC 112, first paragraph. In *In re Gay*, 309 F.2d 769 135 USPQ 311 (CCPA 1962), Judge Rich noted at 309 F.2d 316, 135 USPQ 316 that in satisfying the "enablement" requirement of 35 USC 112:

> . . . Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be.

Further, as the court in *Hybritech* noted at 802 F.2d 1384, 231 USPQ 94:

> Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention, . . . is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive, . . . and is determined as of the filing date of the patent application, . . . (citations omitted).

During the preliminary motions stage of this interference, Staehelin failed to present persuasive, objective evidence that at the time the invention of Secher was made *undue* experimentation would have been required by those skilled in the art to practice Secher's invention. On the other hand, Secher relied on the declaration testimony of Caesar Milstein, Nobel laureate and coauthor of the seminal work in MAB's (Kohler, G. and Milstein, C., *Nature*, (1975) *256*, 495-497, SB, page 15), to the effect that he found the Secher disclosure to be enabling, that Staehelin's position was founded on a "misunderstanding of the science involved", and that the procedure set out in *Nature* (StaX 58) "enables the identification of any antibody binding to interferon-α with sufficient affinity to coprecipitate interferon-α." (Milstein declaration, Paper Number 27, Paragraphs 5 and 7, respectively). Further, as the discussion immediately below will indicate, our reviewing court and this Board have concluded that the preparation and isolation of MAB's to a wide variety of antigens was well-known in the art in April 1980 at the time Secher's invention was made.

Our reviewing court in *Hybritech* noted in discussing the quality of the patent-in-suit's enabling disclosure at 802 F.2d 1384, 231 USPQ 94 that:

> The record fully supports the '110 patent's statement that
> The monoclonal antibodies used for the present invention are obtained by the [hybridoma] process discussed by Milstein and Kohler. . . . The details of this process are well known and not repeated here.

We note that the patent-in-suit in *Hybritech* was filed on August 4, 1980 and thus, was filed after Secher's U.S. application was filed. Nonetheless, the article by Kohler and Milstein was published in 1975. In discussing the state of the art of the screening step of Kohler and Milstein's seminal work, the court continued at 802 F.2d 1384, 231 USPQ 94 that:

> With respect to screening, the only permissible view of the evidence is that screening methods used to identify the necessary characteristics, including affinity, of the monoclonal antibodies used in the invention were known in the art and that the '110 patent contemplated one of those. At trial, Monoclonal's counsel stated "it is a procedure that was known in '78".

In *Ex parte* Erlich, 3 USPQ2d 1011, 1014 (BPAI 1987), this Board, in discussing the state of the art of preparing MAB's to human fibroblast interferon in an application for patent filed in November 1981, noted with respect to the screening of the hydribomas for MAB production that:

> . . . the record is clear that one of ordinary skill in the art may screen the hybridomas produced in the present invention for monoclonal antibody production using other, well known assays;

The Board in *Erlich* continued at 3 USPQ2d 1015 that:

> We find that the claims on appeal differ from the above described prior art only in the use of human fibroblast interferon as the starting antigen in immunizing the animal. However, it is our finding that once the antigen of interest is selected, the use of that antigen in the known method of Kohler and Milstein will result in the expected hybrid cell lines and the specific monoclonal antibodies.

Thus, the reference to Kohler and Milstein evidences that the technology discussed was well-known in the relevant time period, that is, April 1980. Indeed, the Board in *Erlich*, at 1015 discussed the Secher *Nature* article (StaX 58) here in issue, noting:

> The level of skill in this art is adequately represented by the Secher publication which shows that the basic method of Kohler and Milstein may be readily used and adapted for various antigens *such as an interferon.* (emphasis added).

In discussing the conventionality of screening hybridomas for antibody production, the Board in *Erlich*, at page 1016, found that:

> . . . . The obtention of a large number of hybrid cells at the fusion step and the necessity of screening them for the desired antibody production *has been routine in this art since the work of Kohler and Milstein.* (emphasis added).

To the extent Staehelin have relied on *Ex parte* Old, 229 USPQ 196 (BPAI, 1985) for the proposition that the obtention of MAB's was recognized as "unpredictable" in 1980, we simply note that the Board in *Erlich* distinguished *Old* from the case before it based on their facts available in *Erlich* but not available in *Old*.

In *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court, in discussing the question of enablement raised by the

disclosure of the application in issue, noted at 858 F.2d 736, 737, 8 USPQ2d 1404 that:

> Enablement is not precluded by the necessity for some experimentation such as routine screening.

The court then went on to analyze the factors to be considered in determining whether a disclosure would require undue experimentation and ultimately concluded that the Wands application, which was filed in September 1980, was based on an enabling disclosure which did not require undue experimentation.

At 858 F.2d 740, 8 USPQ2d 1406, the court found that:

> The record indicates that cell fusion is a technique that is well known to those of ordinary skill in the monoclonal antibody art, and there has been no claim that the fusion step should be more difficult or unreliable where the antigen is HBsAg than it would for other antigens.

and that:

> . . . There was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known.

and additionally that:

> . . . Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody.

Ultimately, the court concluded that:

> . . . Furthermore, in the monoclonal antibody art it appears that an "experiment" is not simply the screening of a single hybridoma, but is rather the entire attempt to make a monoclonal antibody against a particular antigen. This process entails immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics.

The technology discussed by the *Wands* court above was obviously the technology described originally by Kohler and Milstein in 1975.

Additionally, there is testimony in the record from Dr. Pestka indicating that the procedures used by Staehelin were within the ordinary skill of the routineer in the art in 1979. Specifically, at StaR, page 324, paragraph 8, Dr. Pestka noted that:

> During his January 1979 visit, Dr. Staehelin and I discussed the collaborative research effort for obtaining leukocyte interferon. As part of that research collaboration Dr. Staehelin indicated to me that his laboratory in Roche-Basle would prepare monoclonal antibodies against leukocyte interferon *by conventional hybridoma technology*.

In light of the various quotes from the decisions noted above, we conclude that the "conventional hybridoma technology" referred to by Dr. Pestka included the technology of Kohler and Milstein and, therefore, that the technology was also well-known at the time Secher's invention was made in 1980.

Accordingly, we conclude that Staehelin have failed to meet their burden of making out a *prima facie* case of non-enablement. In so-concluding, we have not overlooked the testimony of Staehelin's various experts, which testimony reaches the conclusion opposite from our own on this issue. However, we are convinced that Staehelin's experts, like Staehelin, applied an improper standard to Secher's disclosure in measuring what Secher's disclosure fairly taught the person of ordinary skill in the MAB art in 1980. Representative of the improper standard applied by Staehelin's experts is the testimony of Dr. Eisen at StaR, page 499 wherein he stated:

> If Dr. Secher were to repeat it *exactly* as he had carried it out in Nature [British I], the same antigenic preparation used for immunization and screening, since he got one monoclonal antibody out of the procedure I think there is a good chance he would get another one *but not a certainty*. On the other hand, if I were to repeat it, based on the information in there, I would not feel that my prospects would be — let me put it this way — *I think anybody else repeating it could not be assured of obtaining the same kind of results*. (emphasis added)

As we have stated above, the enablement requirement does not require exact reproduction of the results obtained by Secher in British I, only objective enablement without resort to undue experimentation is required. Moreover, Secher's experts presented countervailing testimony which reached the opposite conclusion from Staehelin's experts' conclusions. Thus, on balance, the additional evidence adduced by the parties' experts does not mandate any change in the EIC's conclusions below denying Staehelin's motions for judgment on the grounds that Secher's claims are unpatentable under 35 USC 112, first paragraph.

To the extent that Staehelin relies on the decision in *Wands, supra*, for the proposition that the court held Wands' disclosure to be representative of the type of disclosure *required* by 35 USC 112, first paragraph, we simply note that there is no such holding in the case. Rather, the court simply held that the disclosure, held to be inadequate by the Board of Patent Appeals and Interferences for lack of enablement for failure to deposit what the Board considered to be an essential microorganism and as requiring undue experimentation, was enabling in view of the state of the art at the time Wands' invention was made and in view of the high level of skill of the routineer in the art at the time Wands' invention was made. Staehelin has failed to direct our attention to that portion of the decision in *Wands* which stands for the proposition that the court considered the Wands' disclosure the minimum disclosure required to meet the requirements of 35 USC 112, first paragraph.

We reject Staehelin's attempt to discredit Dr. Novick's testimony because she had obtained her Ph.D. in 1979, about the time Secher's invention was made. As the Board held in *Ex parte Hiyamizu*, 10 USPQ2d 1393 (BPAI 1988) with respect to the hypothetical person of ordinary skill in the art:

> . . . It is our view that such a hypothetical person is no more definable by way of credentials than is the hypothetical "reasonably prudent man" standard found in laws pertaining to negligence.

Accordingly, we have considered Dr. Novick's testimony in the context of testimony from an expert, just as we have considered Dr. Eisen's testimony, based on each witness' education, professional training, professional experience and credentials. To the extent Staehelin's experts have given a basis in the evidence for their opinions[5], we do not consider that the evidence adduced from their testimony overcomes the equally persuasive evidence adduced from Secher's experts.

Issue 1) — Written Description of Secher's Patent Disclosure

Staehelin's attack on the disclosure in Secher's British I as failing to meet the written description requirement of 35 USC 112, first paragraph, does not withstand analysis. Staehelin has failed to discharge its burden of proving that British I does not "describe" the subject matter later claimed by Secher in its U.S. application. *Wagoner v. Barger*, 463 F.2d 1377, 175 USPQ 85 (CCPA 1972).

[5] Even the opinion of experts must find a foundation in the evidence. *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985); *In re Grunwell*, 609 F.2d 486, 203 USPQ 1055 (CCPA 1979); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967).

An earlier filed foreign patent application must comply with the requirements of 35 USC 112, first paragraph, if the later filed U.S. application claiming the same invention as in the foreign application is to be accorded benefit under 35 USC 119. *Vogel v. Jones*, 486 F.2d 1068, 179 USPQ 425 (CCPA 1973); *Kawai v. Metlesics, supra*. The written description requirement of 35 USC 112, first paragraph, is separate from the enablement requirement found in the same provision of 35 USC 112. *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984).

[3] The function of the "written description" requirement of 35 USC 112, first paragraph, is to ensure that applicants had possession, as of the filing date of the application relied on, of the subject matter later claimed by them. *In re Blaser*, 556 F.2d 534, 194 USPQ 122 (CCPA 1977). The inquiry into satisfaction of the written description requirement is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. *In re Wertheim*, 646 F.2d 527, 191 USPQ 90 (CCPA 1976). Satisfaction of the "written description" requirement *does not* require *in haec verba* antecedence in the originally filed application. *In re Lukach*, 440 F.2d 1263, 169 USPQ 795 (CCPA 1971). The question is whether one following applicant's specification would necessarily select the later claimed subject matter. *Freerksen v. Gass*, 21 USPQ2d 2007 (BPAI 1990). The question, therefore, is whether the originally filed application would have reasonably conveyed to a person of ordinary skill in the art that applicants invented the subject matter later claimed by them including the limitations in question. *In re Smythe*, 480 F.2d 1376, 178 USPQ 279 (CCPA 1973).

Page 1 of the British I application[6] discloses:

> In this paper we describe the properties of a *monoclonal antibody* to an antigen not available in pure form for screening assays and present in immunizing material at a concentration of 0.1-1% of the total protein injected. The *antigen is human leukocyte interferon*, a protein (or group of proteins) that confers antiviral protection on human cells *in vitro* and *in vivo*. (emphasis added)

Further, at page 2, British I discloses:

> We report here the *isolation of a hybrid myeloma, secreting antibody to human*

[6] The parties agree that the British I application corresponds exactly to the *Nature* article, StaX 58. (StaB, page 8; SB, pages 4 and 16).

leukocyte interferon; and show that this antibody can be used for the purification of interferon by immunoadsorption. (emphasis added)

At page 3, the specification discloses immunizations utilizing mice. Thus, we conclude that Secher's disclosure in British I would have reasonably conveyed to a person possessing ordinary skill in the art that Secher possessed the genus later claimed by them in their U.S. application in the sense of 35 USC 112, first paragraph. That is, British I describes a monoclonal antibody, produced by a hybridoma derived from a mouse and which monoclonal antibody is capable of specifically binding to at least one antigenic determinant of interferon-α."

To the extent Staehelin's argument that the disclosure in British I is inadequate because the specification does not describe the exact details for preparing every species within the genus described, we note that the law does not require such exemplification or detail. Compare *Utter v. Hiraga*, 845 F.2d 993, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988). Staehelin's position on Secher's written description for its claims which correspond to the count appears to parallel the position enunciated by the court in *Kennecott v. Kyocera*, 835 F.2d 1419, 5 USPQ2d 1194 (Fed. Cir. 1987) wherein the court stated at 835 F.2d 1421, 5 USPQ2d 1197 that:

> . . . The purpose of the description requirement of this paragraph [35 USC 112, first paragraph] is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined.

However, in *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991), the court noted at 935 F.2d 1563, 1564, 19 USPQ2d 1117 that:

> To the extent that *Kennecott* conflicts with *Wilder*, we note that decisions of a three-judge panel of this court cannot overturn precedential decisions. . . . This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.* (citations omitted)

Therefore, based on all of the above, we conclude that Staehelin has failed to meet its burden of proving that British I fails to comply with the "written description" requirement of the first paragraph of 35 USC 112.

Issue 1) — Best Mode Disclosed in Secher's Patent

[4] Staehelin's motion for judgment on the grounds that Secher's claims were unpatentable under 35 USC 112, first paragraph, *did not* include *any* argument or evidence that the alleged unpatentability was founded on a failure to satisfy the "best mode" requirement of the first paragraph. Accordingly, we will not now consider Staehelin's arguments concerning the alleged failure of Secher's disclosure to satisfy the "best mode" requirements of the first paragraph of 35 USC 112 raised for the first time in this interference in Staehelin's brief at final hearing. 37 CFR 1.655(b).

Issue 4) — Secher's Motion for Benefit

We conclude that Secher's motion for benefit under 35 USC 119 was properly granted. Indeed, to be accorded benefit for *priority* purposes, Secher's British I need only have disclosed *an* embodiment (species) within the subject matter of the generic count to serve as a prior constructive reduction to practice. *Squires v. Corbett*, 560 F.2d 424, 194 USPQ 513 (CCPA 1977); *Hunt v. Treppschuh*, 523 F.2d 1386, 187 USPQ 426 (CCPA 1975); *Kawai v. Metlesics, supra.* The example in British I is a species within the subject matter of the count and thus serves as a constructive reduction to practice.

Issue 2) — Staehelin's Motion for Judgment

Since we have concluded that British I satisfies the requirements of 35 USC 112, first paragraph, and since we have concluded that Secher was properly accorded benefit of British I for priority purposes, none of the references denominated as "prior art" (references 3) through 6) in Staehelin's motion for judgment, Paper Number 13) are, in fact, "prior art" with respect to Secher and, therefore the motion was and is properly denied based on those references. With respect to the references denominated as 1) and 2) in the motion for judgment, although Staehelin states in its brief at page 39 that Staehelin "renew at Final Hearing its Paper No. 13 motion for judgment", Staehelin has not specifically argued that there is any new evidence not available during the motions period which requires overturning the presumptively correct decision by the EIC, 37 CFR 1.655(a), that references 1) and 2) neither anticipated (35 USC 102) nor rendered obvious (35 USC 103) Secher's claims corresponding to the count. Indeed, Staehelin has failed to even mention references 1) and 2) in its brief or reply brief as references 1) and 2) relate to the motion for judgment. Accordingly, we conclude that Staehelin's motion for judgment based on references 1) and 2) was and is properly denied.

Issue 3) — Secher's Motion for Judgment

Secher's motion for judgment (Paper Number 18) is said by Secher to be renewed in its brief (SB, the paragraph bridging pages 62 and 63). However, the decision by the EIC below in denying said motion is presumptively correct, 37 CFR 1.655(a). Nothing in Secher's brief overcomes the presumption of correctness accorded the EIC's decision below. Indeed, the "renewed" motion appears to be little more than a reargument of the arguments made in the motion for judgment and are based on Secher's "renewed" arguments to deny Staehelin benefit of its Swiss priority applications (SB, page 62, last full paragraph). Suffice it to say that there is nothing in the way of newly presented evidence or argument which would require that we overturn the EIC's presumptively correct decision in granting Staehelin's motion for benefit.

Issue 5) — PRIORITY

As a result of the granting of Secher's motion for benefit of their earlier filed British applications, Staehelin, as the junior party whose application was copending with Secher's application which matured into U.S. Patent Number 4,423,147, bears the burden of proving its case for priority by a preponderance of the evidence. *Morgan v. Hirsch*, 728 F.2d 1449, 221 USPQ 193 (Fed. Cir. 1984); *Peeler v. Miller*, 535 F.2d 647, 190 USPQ 117 (CCPA 1976).

In order to be awarded priority in this interference, Staehelin must prove an actual reduction to practice prior to April 11, 1980, Secher's constructive reduction to practice, or prove a conception of the subject matter of the count before Secher's effective filing date of April 11, 1980, coupled with reasonable diligence just prior to April 11, 1980, up to a reduction to practice (constructive or actual) by Staehelin. *Jepson v. Egly*, 231 F.2d 947, 109 USPQ 354 (CCPA 1956); *Hull v. Davenport*, 24 CCPA (Patents) 1116, 90 F.2d 103, 33 USPQ 506; *Wilson v. Sherts*, 21 F.2d 1070, 28 USPQ 379 (CCPA 1936).

CONCEPTION

[5] Staehelin conceived of its invention in Switzerland (StaR, ¶6, StaB, pages 11 and 46) and, therefore, may not rely on evidence of such conception for purposes of proving priority. 35 USC 104, first sentence. However, Staehelin may still be awarded priority by proving by a preponderance of the evidence an introduction of conception into the United States prior to Secher's constructive reduction to practice coupled with reasonable diligence from a time period just prior to Secher's entry into the field up to a reduction to practice by Staehelin. *Shurie v. Richmond*, 699 F.2d 1156, 216 USPQ 1042 (Fed. Cir. 1983) and *Breuer v. DeMarinis*, 558 F.2d 22, 194 USPQ 308 (CCPA 1977).

Staehelin urges in its brief that introduction of conception into the United States prior to April 11, 1980, the date of Secher's constructive reduction to practice, occurred in January 1979. Specifically, Staehelin urges that Dr. Staehelin disclosed his conception of the subject matter of the count to Dr. Pestka during Dr. Staehelin's visit to the Nutley, New Jersey facility of Hoffman-La Roche in January 1979. Evidence of introduction of conception is said to be found at StaR, page 2, ¶'s 6, 8 and 9 and StaR, page 324, ¶'s 7 and 8 (StaB, page 46). The "evidence" at StaR, page 2, ¶'s 6, 8 and 9 is the uncorroborated testimony of Dr. Staehelin, one of the coinventors, and relates to activity in Switzerland and, thus, may not be relied on as evidence of introduction of conception. 35 USC 104; *Gould v. Schawlow*, 363 F.2d 968, 150 USPQ 634 (CCPA 1966). However, the evidence at StaR page 324, ¶'s 7 and 8, is the testimony of Dr. Pestka wherein he recalled what Dr. Staehelin and he had discussed during Dr. Staehelin's January 1979 visit.

Paragraph 8 of the cited testimony from StaR, page 324 sets forth the specifics of Dr. Pestka's recollections. Therein, Dr. Pestka revealed that he and Dr. Staehelin discussed a collaborative research effort for obtaining leukocyte interferon (interferon-α). Dr. Pestka testified that Dr. Staehelin's contribution would be the preparation of MAB's against leukocyte interferon by "conventional hybridoma technology". Dr. Pestka additionally testified that he undertook to supply the leukocyte interferon to Dr. Staehelin which was necessary for immunizing the mice as the first step in obtaining hybridoma

cell lines (StaR, ¶8, page 325). Accordingly, we consider that Dr. Pestka's testimony establishes introduction of conception by Staehelin into this country sometime after January 9, 1979 (the date Dr. Staehelin's visit was to begin, StaX 30) and before January 26, 1979, the date Dr. Pestka received a letter from Dr. Staehelin in Switzerland (StaX 4).

We have not overlooked Secher's argument in its brief that Dr. Pestka's testimony cannot be considered to support a finding that conception was introduced into the United States because "the testimony of Dr. Pestka (StaR 324-349) is devoid of any evidence that the information provided to Dr. Pestka by Dr. Staehelin was sufficient to enable him to reproduce the work and obtain the invention defined by the Count herein." (SB, page 64). Nonetheless, the testimony of Dr. Pestka indicates that Dr. Staehelin's lab was working on preparing MAB's to leukocyte interferon by "conventional hybridoma technology". By now it should be abundantly clear that "conventional hybridoma technology" included the technology of Kohler and Milstein.

Lest there be any doubt of how Dr. Staehelin's lab was preparing the hybridomas, we have Dr. Pestka's testimony that he (Dr. Pestka) "undertook to supply leukocyte interferon prepared at Nutley to Dr. Staehelin for his use in immunizing mice . . ." (StaR, page 325). Clearly, the leukocyte interferon was to be used as the antigen for inducing the immune response in the mice, which mice would be sacrificed to obtain their spleen cells for fusion with the myeloma cells to obtain the hybridomas.

[6] Neither have we overlooked Secher's argument that the introduction of conception was by only one of the named inventors and, thus, could not serve as evidence of introduction of conception. However, it has been held that evidence of conception naming only one of the actual inventive entity inures to the benefit of and serves as evidence of conception by the complete inventive entity. *Haskell v. Colebourne*, 671 F.2d 1362, 213 USPQ 192 (CCPA 1982).

REDUCTION TO PRACTICE

Staehelin asserts that it introduced an actual reduction to practice of the subject matter of the count into the United States on May 22, 1980 when Dr. Staehelin sent to Dr. Pestka nine of eleven MAB's Dr. Staehelin had produced from mouse hybridomas and as evidenced by Dr. Pestka's testimony at StaR, pages 331 and 332, and ¶'s 32 through 34 and StaX 19. *Shurie v. Richmond; Breuer v. DeMarinis; supra.*

StaX 19 is a two-page letter from Dr. Staehelin to Dr. Pestka dated May 13, 1980 and which bears a receipt stamp indicating "RECEIVED MAY 22 1980 S. PESTKA". The letter has attached thereto two sheets, StaX 19A and StaX 19B. StaX 19A is a summary sheet outlining "the most important characteristics" of the eleven MAB's discussed in the letter. StaX 19B is a "representative neutralization experiment" wherein one of the MAB's ability to inhibit the antiviral activity of leukocyte interferon was determined.

Staehelin also asserts that Drs. Staehelin and Pestka reduced to practice the subject matter of the count in early June 1980 when Dr. Staehelin was again visiting Dr. Pestka at his lab in New Jersey when he and Dr. Pestka ran a series of immunoassays for interfon-α using the MAB's designated as LI-1 and LI-9 in Dr. Staehelin's letter of May 13, 1980. StaB, page 47. Staehelin urges that Dr. Pestka corroborated this reduction to practice by his testimony at StaR, page 336, ¶43 and StaR, page 338, ¶47.

[7] We disagree with Staehelin that receipt in Nutley, New Jersey of the nine MAB's by Dr. Pestka along with Dr. Staehelin's explanatory letter with the attachments which characterized the nature of the MAB's constituted an introduction of an actual reduction to practice of the subject matter of the count into the United States by at least May 22, 1980. *Shurie v. Richmond* and *Breuer v. DeMarinis, supra*, relied on by Staehelin in support of its position do *not* stand for the proposition argued.

As the court in *Shurie* noted at 699 F.2d 1158, 216 USPQ 1044, "An actual reduction to practice in Canada is irrelevant in an interference proceeding concerning priority of invention." *Breuer*, concerned the burden an applicant was required to meet to make out a *prima facie* case as would entitle him to an award of priority so the interference could go forward under old Rule 204(c). The court stated at 558 F.2d 28, 194 USPQ 313, that Breuer's burden, unlike Staehelin's burden here of a preponderance of the evidence, was "merely to establish a *prima facie* case." More importantly, in *Breuer* there *was* evidence that the compound introduced into the United States and identified as a compound within the count was subjected to testing *in the United States*. See also *Micheletti v. Wignall*, 196 USPQ 858 (Bd.Pat.Int. 1976), especially at 196 USPQ 861, [4]. Accordingly, the attachments to Dr. Staehelin's letter marked as StaX 19A and StaX 19B are not admissible to "establish a date of invention", but are only admissible as evidence to provide the identity of the MAB's introduced into this country. *Breuer v. DeMarinis, supra.*

Nonetheless, the Staehelin record also establishes that Dr.'s Staehelin and Pestka carried out various immunoassays using the MAB's introduced into the United States by Dr. Staehelin and identified by Dr. Pestka as MAB's within the count in this interference in Dr. Pestka's lab in the United States sometime between June 2, 1980 and July 23, 1980. (StaR, pages 333 through 340; StaX 20). We, therefore, agree with the conclusion implicit in Secher's argument in its brief at SB, page 66, that "until such time as Drs. Pestka and Staehelin carried out the immunoassays in June 1980, there was no evidence or assurance that the materials in hand would bind to antigenic determinants of human interferon-α," and that some evidence of activity in the United States establishing utility for the MAB's introduced and identified was required to establish an actual reduction to practice.

We conclude that the Staehelin record establishes that on June 2, 1980, the MAB's imported into the United States did bind to antigenic determinants of human interferon-α and, thus, Staehelin has established an actual reduction to practice in the United States no later than June 2, 1980. However, since an actual reduction to practice on June 2, 1980 is subsequent to the filing date of Secher's British I priority application, Staehelin must show that it was reasonably diligent *in the United States* from a time just prior to Secher's entry in the field, that is, April 11, 1980, up to the time of its actual reduction to practice in June 1980 in order to be awarded priority for the subject matter of the count, *Jepson v. Egly; Hull v. Davenport; Wilson v. Sherts, supra.*

DILIGENCE

[8] Where diligence is involved in the determination of priority, each case rests and must be decided on its own facts, taking into consideration all of the surrounding circumstances. *Wilson v. Sherts, supra.* The evidence relied on to show "reasonable diligence" must ordinarily be directed to reduction to practice of the invention of the counts in issue. *Naber v. Cricchi*, 567 F.2d 382, 196 USPQ 294 (CCPA 1977). The party chargeable with diligence must account for the *entire* period during which diligence is required, *Gould v. Schawlow, supra*, or acceptable excuses or reasons for failure to take action must be presented, *Hull v. Davenport, supra.* Testimonial evidence by the inventor or inventors must be adequately corroborated. *Gould v. Schawlow, supra.* If documentary evidence is relied on to establish reasonable diligence, it must show specific acts at specific times directed at a reduction to practice of the invention of the count. *Naber v. Cricchi, supra.* Activities abroad *will not* be considered for the purposes of establishing diligence in reducing an invention to practice. 35 USC 104; *Wilson v. Sherts, supra.*

Here, the critical time period in question is from just prior to Secher's entry in the field on April 11, 1980 up to Staehelin's actual reduction to practice on June 2, 1980. The Staehelin record, brief and reply brief are devoid of *any* evidence of *any* activity in this country by the inventors or any activity on their behalf in this country towards a reduction to practice of the invention of the count. Quite the contrary, the only evidence of any activity by the inventors during the critical time period in question may be found at StaR, page 18, ¶41, wherein Dr. Staehelin testified that the inventors:

> developed in *Basle* during the period April 1 through May 31, 1980 a procedure for radiolabeling the monoclonal antibodies produced in Exhibit 16 with ^{125}I in order to use them in radioimmunoassay for determining the presence and amount of leukocyte interferon. (emphasis added)

That is, all the inventors were in Switzerland during almost the entire critical time period and could not have been "diligent" within the meaning of 35 USC 104 and the well-settled cases interpreting the statute. See also the corresponding statement at StaB, page 14, first full paragraph.

Staehelin's pronouncement at StaB, page 47, lines 23 and 24 to the effect that from April 7, 1980:

> . . . there was diligence from that time to the reduction to practice on May 22, 1980,

does *not* satisfy Staehelin's burden of establishing diligence by corroborated evidence of the inventors' activity in this country towards a reduction to practice of the invention of the count. Indeed, it appears from all the evidence in this interference that the entirety of Staehelin's work prior to introduction into the United States of the samples of the MAB's produced in Switzerland was, in fact, performed outside this country in Switzerland. The law is clear that such activity may not be relied on to establish a date of invention. 35 USC 104. Accordingly, we conclude that Staehelin has not met its burden of persuasion in proving priority of invention of the subject matter of the count.

ISSUE 6)

In light of our decision as set forth fully above, we consider Secher's motion to suppress under 37 CFR 1.656(h) to be moot. The motion is *dismissed*.

JUDGMENT

David S Secher and Derek C. Burke, the senior party, are entitled to their patent containing claims 1 through 7 corresponding to the count. Additionally, Theophil Staehelin, Christian Stahali and Vicenzo Miggiano are not entitled to a patent containing claims 10 through 12, 14, 16 through 21 and 23 through 25 of their application corresponding to the count.

District Court, N.D. Illinois

American Dental Association Health Foundation v. Bisco Inc.

No. 91 C 8035

Decided June 11, 1992

PATENTS

1. Practice and procedure in Patent and Trademark Office — Prosecution — Filing date (§110.0906)

Patentability/Validity — Anticipation — Prior publication (§115.0705)

Patent infringement plaintiff has demonstrated likelihood of success of demonstrating that patent in suit is entitled, under 35 USC 120, to filing date of its parent patent, and that thus patent is not anticipated by article which was published less than one year before that date.

2. Patentability/Validity — Specification — Enablement (§115.1105)

Accused infringer has failed to demonstrate that patent in suit, for method of adhesively bonding materials used to repair teeth, is invalid pursuant to 35 USC 112 for lack of enablement, since defendant has failed to demonstrate even one compound that falls within scope of claim limitation and that is inoperative, since no evidence demonstrates that three licensees of patent had difficulty identifying appropriate compounds for invention, and since language which defendant contends violates Section 112 was specifically suggested for inclusion by Patent and Trademark Office.

3. Infringement — Literal infringement (§120.05)

Patent infringement plaintiff has demonstrated likelihood of success of demonstrating that its patent for method of adhesively bonding materials used to repair teeth is infringed by accused dental restorative kit, in view of defendant's failure to rebut plaintiff's clear showing that kit directly infringes patent claim which calls for separate containers for each compound.

REMEDIES

4. Non-monetary and injunctive — Equitable relief — Preliminary injunctions — Patents (§505.0707.07)

Showing, by non-profit foundation that uses royalties from its inventions to fund future dental research, that it is losing royalty income both from alleged infringer's sale of its dental restorative kit and from its licensees' threats to suspend royalty payments, and that such lost income hinders its research efforts, constitutes sufficient showing of irreparable harm to warrant issuance of preliminary injunction, nor is such relief precluded by foundation's delay, since such delay was due to its good faith decision to seek settlement of lawsuit; public interest also favors injunction, since such relief will prevent foundation from having to restrict its research efforts, and since public will not be deprived of dental restorative kits, in view of ability of foundation's licensees to satisfy market's demand for product.

Particular patents — Chemical — Dental repair

4,659,751, Bowen, simplified method for obtaining strong adhesive bonding of composites to dentin, enamel, and other substrates, preliminary injunction issued.

Action by American Dental Association Health Foundation against Bisco Inc. and Byoung Suh for patent infringement. On plaintiff's motion for a preliminary injunction. Motion granted.

Allegretti & Witcoff, Ltd. (Jon O. Nelson, Edward W. Remus, and Barbara A. Heaphy, of counsel), Chicago, Ill., for plaintiff.

Marshall, O'Toole, Gerstein, Murray & Bicknell (Basil P. Mann, Richard A. Schnurr, and Christine A. Dudzik, of counsel), Chicago, for defendants.

Kocoras, J.

This matter is before the Court on plaintiff's motion for a preliminary injunction. Plaintiff's motion is pursuant to Federal Rule of Civil Procedure 65(a) and 35 U.S.C.A. § 283 (West 1984). For the reasons set forth below, we grant the motion.

I. BACKGROUND

Plaintiff, American Dental Association Health Foundation ("Foundation"), filed this patent infringement suit against defendant Bisco, Inc. and Byoung Suh (collectively "Bisco"). The patent at issue is U.S. Patent Number 4,659,751 ("the '751 patent").

Foundation is a not-for-profit corporation, headquartered in Chicago, that sponsors dental research. Foundation does not commercially manufacture any dental products resulting from its research. Rather, it licenses its patented technology to independent dental supply houses. These licensees then remit royalties to Foundation which fund additional dental research and public interest activities.

Dr. Rafael Bowen is Foundation's director. Dr. Bowen is a researcher who has made significant contributions to the field of dentistry. He is a named author on more than two hundred papers and a named inventor on sixteen United States patents and five foreign patents.

Dr. Bowen invented the invention described in the '751 patent. The patent is entitled "Simplified Method for Obtaining Strong Adhesive Bonding of Composites to Dentin, Enamel and Other Substrates" and has been assigned to Foundation. The patent describes a system for adhesively bonding tooth-colored, generally non-metallic, polymer-based (plastic) materials, used to repair teeth, directly to the hard part of the tooth. This hard part of the tooth is known as "dentin." According to Foundation, this new dentin bonding technology, for the first time, successfully provides a strong adhesive bond of the new plastic-like material to dentin, thereby improving the treatment of many commonly known dental problems such as tooth erosion, cavities, potential dental decay, and tooth fractures. Dr. Bowen's new technology also apparently eliminates a substantial amount of mechanical cutting that was previously required under older methods of dental repair.

Dr. Bowen's dentin bonding research has formed the basis of four patents issued by the Patent and Trademark Office ("PTO"). The two relevant patents for purposes of this opinion are U.S. Patent Number 4,588,756 ("the Parent patent") and the '751 patent. The '751 patent, filed on February 3, 1986, was a continuation-in-part patent to the Parent patent. The Parent patent was filed on February 7, 1985 and is entitled "Multi-Step Method For Obtaining Strong Adhesive Bonding of Composites to Dentin, Enamel, and Other Substrates."[1]

Because of the '751 patent's potential commercial value, Foundation granted five domestic dental supply companies a non-exclusive license to market it. Currently, three licensees actively market the invention to dentists in the form of a dental repair kit. These licensees pay Foundation a seven percent royalty for each kit sold. Since 1984, these royalties have totaled approximately $950,000, derived from more than $12,000,000 in sales. Foundation has used these royalties to fund ongoing research. In order to continue receiving royalties, Foundation must, according to the terms of its licensing agreements, sue any party who significantly infringes the '751 patent.

In furtherance of this contractual obligation, Foundation has brought this suit against Bisco. Bisco is an Illinois corporation that researches, develops, and manufactures dental products for professional use by dentists. The product at issue is Bisco's "ALL-BOND" and "ALL-BOND 2" dental restorative kits. These kits contain various chemical reagents useful in promoting the bonding of dental restorative materials to a variety of dental surfaces including tooth dentin, enamel, and metal dental surfaces. Bisco sells these kits to dentists. Although offered a license to market the '751 patent, Bisco has rejected Foundation's proposal.

Because of Bisco's rejection and its continued marketing of the ALL-BOND and ALL-BOND 2 kits, Foundation filed this patent infringement action. Foundation contends that the production and sale of Bisco's kits infringe at least claims 12 and 42 of the '751 patent in violation of 35 U.S.C. § 271. Claim 12 describes a method for preparing the surface of dentin for bonding with a restorative composite material or resin. Claim 12(a) initially requires that a party contact the dentin surface with "at least one strong acid." Claim 12(b) in turn then requires

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[1] The Parent patent, like the '751 patent, was a continuation-in-part patent to Patent Number 4,521,550 which Dr. Bowen filed on July 25, 1983. The '550 patent, in turn, was a continuation-in-part patent to Patent Number 4,514,527 which was filed on January 10, 1983.

APPENDIX D'

SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES

Contents

SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES

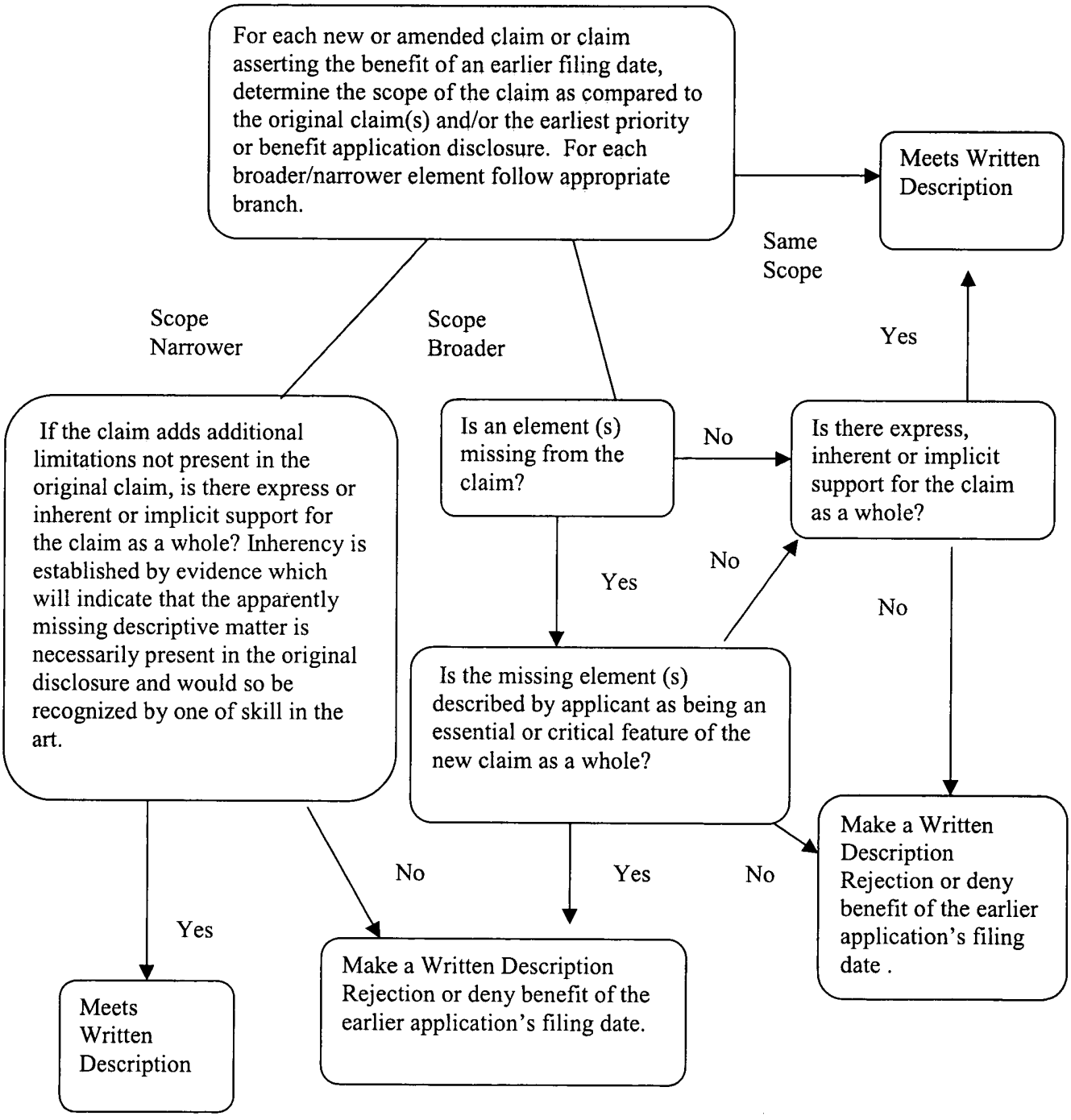
It is assumed at this point in the analysis that the specification has been reviewed and an appropriate search of the claimed subject matter has been conducted. It is also assumed that the examiner has identified which features of the claimed invention are conventional taking into account the body of existing prior art. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. If the examiner determines that the application does not comply with the written description requirement, the examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. It should also be noted that the test for an adequate written description is separate and distinct from the test under the enablement criteria of 35 U.S.C. § 112 first paragraph. The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, para. 1, for lack of adequate written description. Limitations may not, however, be imported into the claims from the specification.

The following examples only describe how to determine whether the written description requirement of 35 U.S.C. 112, para. 1 is satisfied. Regardless of

the outcome of that determination, Office personnel must complete the patentability determination under all the relevant statutory provisions of Title 35 of the U.S. Code. Once Office personnel have concluded analysis of the claimed invention under all the statutory provisions, including 35 U.S.C. 101, 112, 102, and 103, they should review all the proposed rejections and their bases to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions, and reasons which support them. When possible, the Office action should offer helpful suggestions on how to overcome rejections.

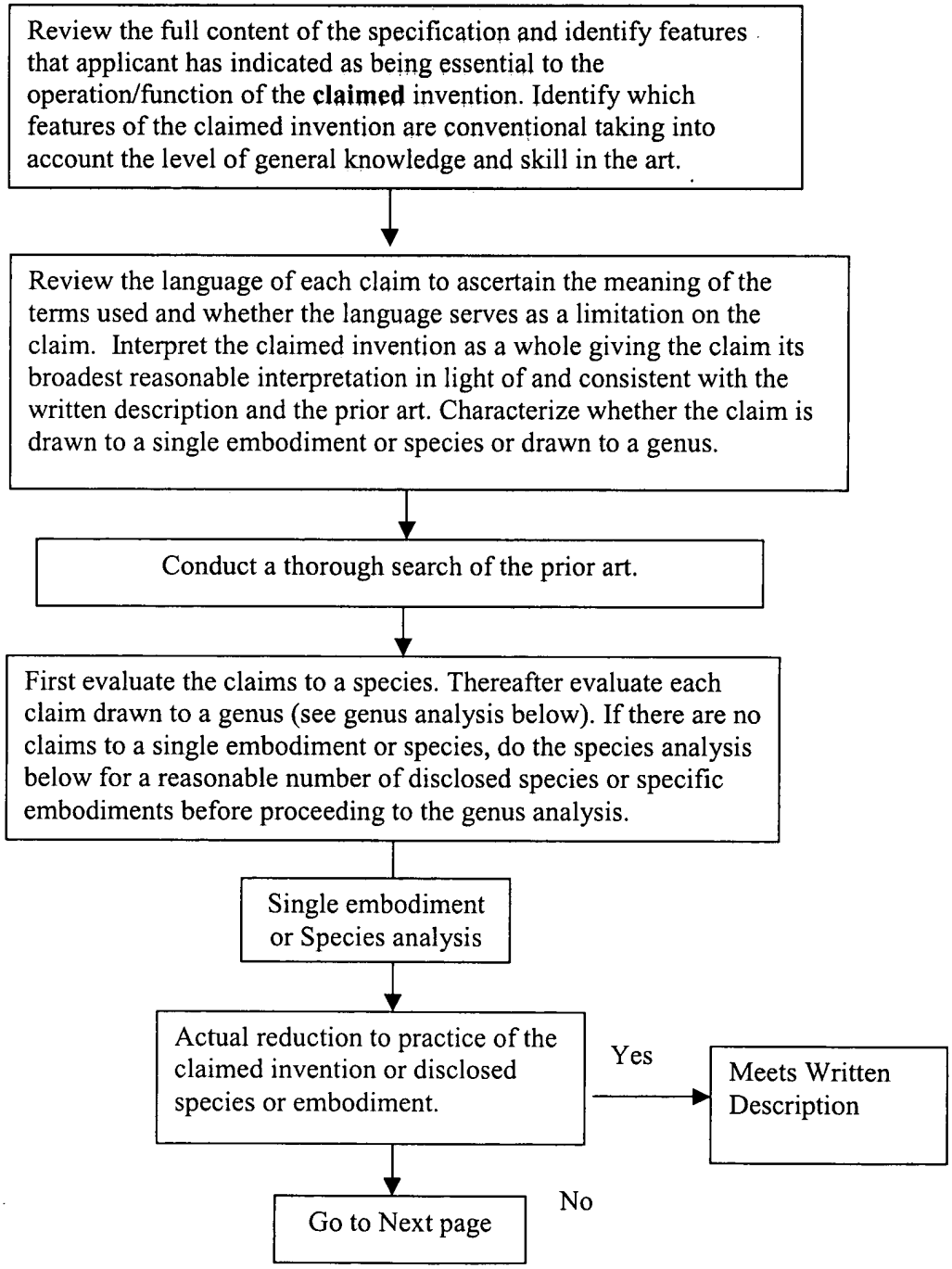
Written Description Amended or New Claims, or Claims Asserting the Benefit of an Earlier Filing Date

Decision Tree



Written Description
Original Claims

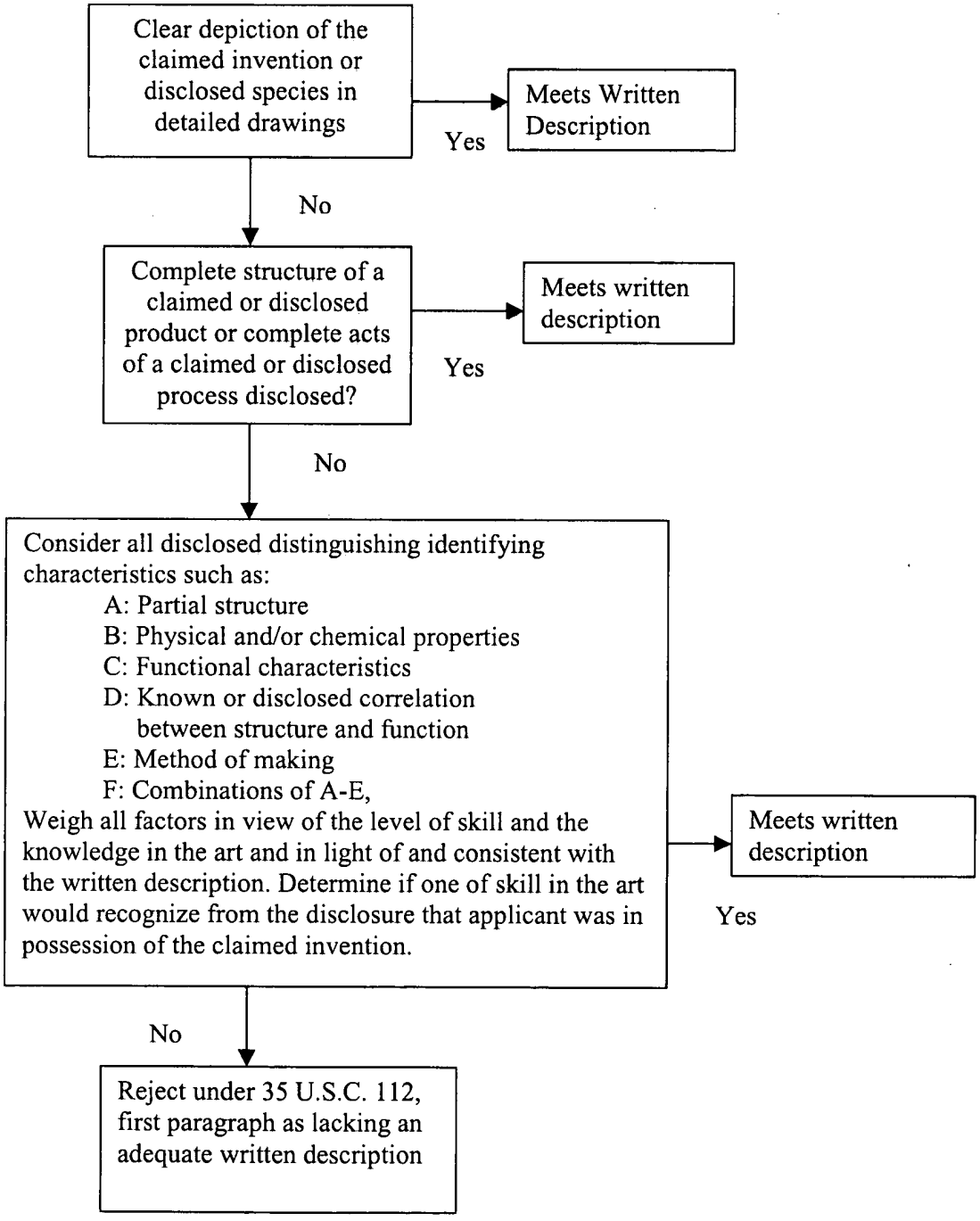
--Decision Tree--



Written Description

Original Claims

--Decision Tree--

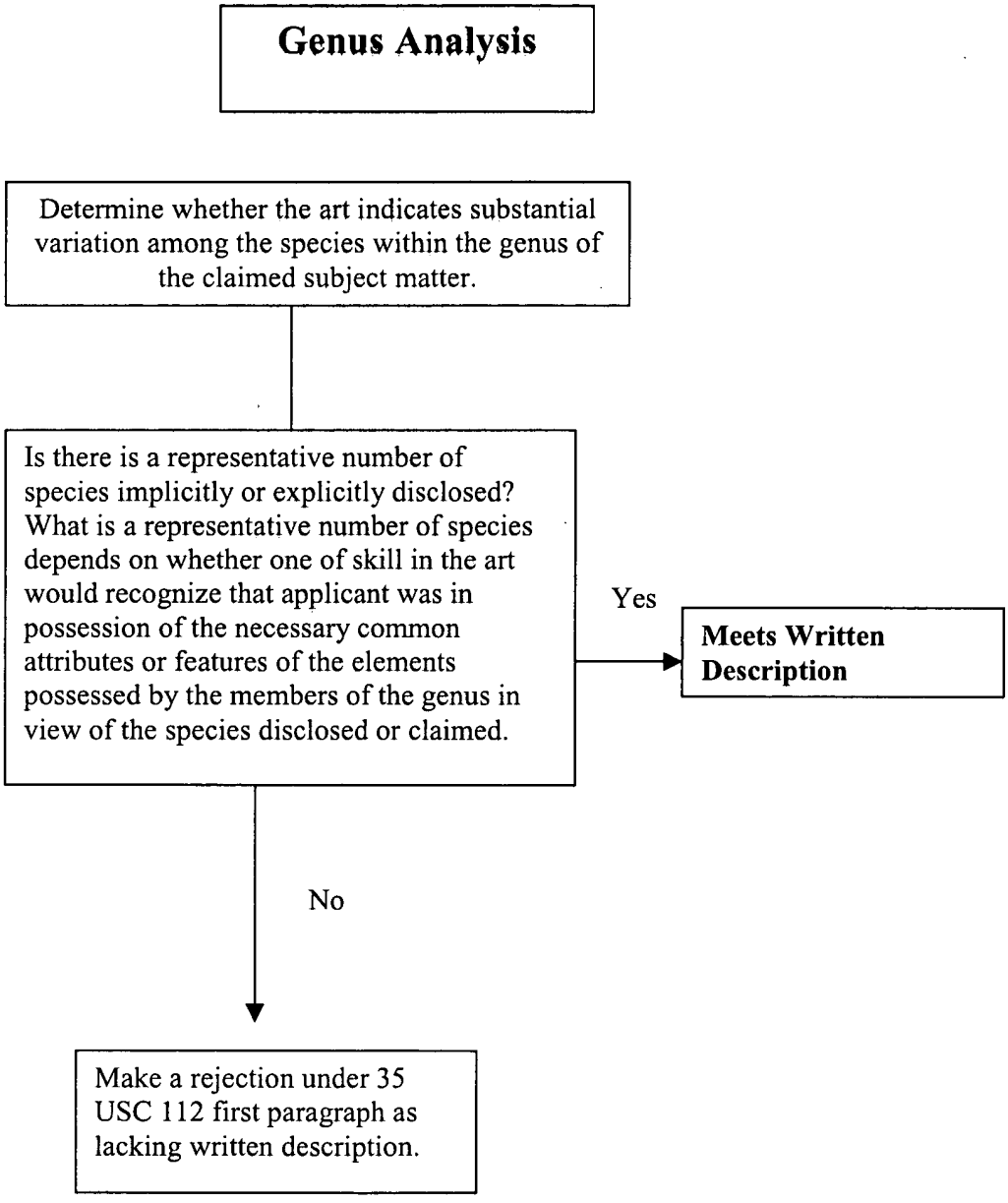


Written Description

Original Claims

Decision Tree

--Page 3--



WRITTEN DESCRIPTION TRAINING EXAMPLES

Example 1: Amended claims

Fact Pattern:

The specification is directed to a sectional sofa with a console between two reclining chairs, wherein control means for the reclining chairs are mounted on the console. The original disclosure clearly identifies the console as the only possible location for the controls, and provides for only the most minor variation in the location of the controls, e.g., the controls may be mounted on the top or side surfaces of the console or on the front wall. Additionally, the specification states that the purpose for the console is to house the controls. The original claims required the control elements to be present in the console. Applicant subsequently amends the claims to remove this limitation.

Amended Claim:

1. (Amended) A sectional sofa comprising:

a pair of reclining seats disposed in parallel relationship with one another in a double reclining seat sofa section, said double reclining seat sofa section being without an arm at one end whereby a second sofa section of the sectional sofa can be placed in abutting relationship with the end of the double reclining seat sofa section without an arm so as to form a continuation thereof,

each of said reclining seats having a backrest and seat cushion and movable between upright and reclined positions, said backrests and seat cushions of the pair of reclining sets lying in respective common planes when the seats are in the same positions,

a fixed console disposed in the double reclining seat sofa section between the pair of reclining seats and with the console and reclining seats together comprising a unitary structure, said console including an armrest portion for each of the reclining seats, said arm rests remaining fixed when the reclining seats move from one to another of their positions, and

a pair of control means [located upon the center console to enable each of the pair of reclining seats to move separately between the reclined and upright positions] mounted on the double reclining seat sofa section and each readily accessible to an occupant of its respective reclining seat and when actuated causing the respective reclining seat to move from the upright to the reclined position.

Analysis:

The amended claim is broader than the original claim in that the pair of control means is no longer required to be located on the center console. Thus, control means mounted on a center console is an element missing from the claim. The specification describes the location of the control means on the console as an essential feature of the claimed invention as a whole because the specification clearly identifies the console as the only possible location for the controls, and states that the purpose for the console is to house the controls.

Conclusion:

Reject the amended claim under 35 USC §112 first paragraph as lacking adequate written description.

Example 2: 35 USC 120 Priority

Fact Pattern:

The specification is directed to artificial hip sockets that include cup implants adapted for insertion into an acetabular, or hip, bone. The specification indicates that the shape of the cup is not important, as long as the implant can effectively function as an artificial hip socket. The application is a continuation in part of a parent application that describes an acetabular cup prosthesis wherein the cup is a trapezoid, a truncated cone, or of conical shape. All of these terms describe a conical cup. The parent specification also touts the criticality of a conical cup over all other shape cups.

A reference disclosing the claimed invention published between the filing date of the parent application and the instant application. Applicant asserts entitlement to the filing date of the parent application.

Claim:

1. An acetabular cup prosthesis comprising (1) a body extending generally longitudinally and terminating into front and rear surfaces, said front surface extending substantially transversely to said body; and (2) at least one fin for securing said cup to a prepared acetabulum cavity, said fin having a length extending generally longitudinally from said front surface toward said rear surface continuously along said body throughout the entire length of said fin, and said fin being configured so as to extend radially outwardly beyond the perimeter of said front surface and said body so as to engage with the cavity thereby securing said cup.

2. The prosthesis of claim 1, wherein the body has a generally conical outer surface.

Analysis:

Claim 1 in the instant application is directed to an acetabular cup prosthesis wherein the shape of the cup is not specifically defined (see element (1) of claim 1). The claim is broader than the disclosure in the parent application, which only describes a conical cup. Claim 1 is missing the element of a conical shape. This element is an essential or critical feature of the invention described in the parent application because the parent application only discloses a conical shape and the conical shape is described as critical over other shapes.

Claim 2 of the instant application is directed to an acetabular cup prosthesis wherein the cup has a generally conical outer surface. The claim is of the same scope as the invention described in the parent application.

Conclusion:

Reject claim 1 over the prior art reference, and indicate that the claim is not entitled to the benefit of the earlier application filing date.

Indicate that claim 2 is entitled to the benefit of the parent application filing date.

Note that if applicant had added the subject matter of claim 1 of this application to the parent application in an amendment, the claim would have been rejected under 35 U.S.C. 112, first paragraph as lacking an adequate written description.

Example 2A: Essential element missing from original claim

Fact Pattern:

The fact situation of example 2 above is similar to the fact situation of the instant example, however, there is no parent application in this example.

The specification is directed to artificial hip sockets that include cup implants adapted for insertion into an acetabular, or hip, bone. The specification indicates that the shape of the cup is critical to permit the implant to effectively function as an artificial hip socket. The application describes an acetabular cup prosthesis wherein the cup is a trapezoid, a truncated cone, or of conical shape. All of these terms describe a conical cup. The specification also touts the criticality of a conical cup.

Claims: Same as claims 1 and 2 of example 2 above.

Analysis:

Claim 1 in the instant application is directed to an acetabular cup prosthesis wherein the shape of the cup is not specifically defined (see element (1) of claim 1). The claim is broader than the disclosure in the instant application that only describes a conical cup. Claim 1 is missing the element of a conical shape. A review of the specification indicates that a cup implant having a shape which can effectively function as an artifical hip socket is critical to the operation/function of the claimed invention. The application discloses a conical shape cup and the conical shape is described as critical over other shapes. The specification indicates that the invention **as claimed** will not function in its intended manner without the specific cup

shape. Therefore this element is essential to the function/operation of the invention.

Claim 1 is directed to a genus. There is no actual reduction to practice or clear depiction of the claimed invention in detailed drawings; however, the complete structure of a species of the claimed prosthesis (with conical shape) is disclosed. The disclosed species is not representative of the genus because the specification indicates that without the conical shape the invention will not operate as intended. Therefore, applicant was not in possession of the necessary common attributes of the elements possessed by the members of the genus. A written description rejection should be made in this situation.

Example 2B: A preferred element missing from original claim

Fact Pattern:

The fact situation of example 2B is similar to example 2A above except that in this example the shape of the conical cup is described as being preferred.

The specification is directed to artificial hip sockets that include cup implants adapted for insertion into an acetabular, or hip, bone. The specification indicates that the shape of the cup must permit the implant to effectively function as an artificial hip socket. The application describes an acetabular cup prosthesis wherein the cup is preferably a trapezoid, a truncated cone, or of conical shape. All of these terms describe a conical cup. The specification emphasizes that a conical cup is the preferred embodiment.

Claims: Same as claims 1 and 2 of example 2 above.

Analysis:

Claim 1 in the instant application is directed to an acetabular cup prosthesis wherein the shape of the cup is not specifically defined (see element (1) of claim 1). The claim is broader than the disclosure in the instant application that only describes a conical cup. Claim 1 is missing the element of a conical shape. A review of the specification indicates that a cup implant having a conical shape is preferred but has no apparent bearing to the operation/function of the claimed invention. Therefore this element is not essential to the function or operation of the invention.

Claim 1 is directed to a genus. Although there is no actual reduction to practice or clear depiction of the claimed invention in detailed drawings, the complete structure of a species of the claimed prosthesis (with conical shape) is disclosed. The disclosed species is representative of the genus because there is a known correlation between the structure and the function of claimed invention and one of skill in the art would recognize that applicant was in possession of the necessary common attributes of the elements possessed by the members of the genus. The invention as claimed will function in its intended manner even without the specific cup shape. No written description rejection should be made in this situation.

Note: ***If the specification needs to be amended to be consistent with an original claim, see MPEP 608.01(o).***

Example 3: New claims

Fact Pattern:

The specification describes a form of computer technology called multi-threading. In essence, computers with multi-threading capabilities can switch between tasks with such rapidity that they appear to be performing two or more tasks at once. The specification describes one illustrative example in the specification wherein one of the program threads is an editor and another thread is a code processing routine in the form of a compiler. As the operator strikes keys at the keyboard, the compiler thread executes between each successive pair of keystrokes to process the entered source code concurrently with the editing operation. By the time the operator has finished entering or editing the code the compiler thread will have completed most of the required processing, thereby freeing the operator from lengthy periods of waiting for extensive code processing.

In this illustrative embodiment the interrupt operation of the central processor is periodically activated by a timer or clock. Each interrupt operation asynchronously preempts the executing compiler thread and passes control of the central processor to an interrupt service routine. The input port is then polled to test if a key has been struck at the keyboard. If not, the interrupt is terminated and control returns to the compiler thread. If polling the port reveals that a key has been struck then the interrupt service routine invokes the editor thread which takes control of the central processor to perform a character code entry or other edit operation. In addition to the description above, the application's abstract references an editor, compiler, interrupt means, and return means, and the "Object of the Invention" section

and the "Description of Prior Art" clearly discuss the importance of an editor and compiler.

The original claims required, *inter alia*, an editor, a compiler, an interrupt means and a return means. These elements are missing from new claim 20.

Claim:

20. A computer-readable disk memory having a surface formed with a plurality of binary patterns constituting a multithreaded application program executable by a desktop computer having a central microprocessor, a memory, means for loading said application program into a defined address space of said memory, and a clock-driven periodically-activated interrupt operation, said multithreaded program comprising

a plurality of sets of instructions with each set executable by said microprocessor,

a first of said sets of instructions executable to provide a first thread of execution having control of the central microprocessor,

said first thread of execution being periodically preempted in response to activations of an interrupt operation at predetermined fixed time intervals, and

a second of said sets of instructions executable to provide a second thread of execution to acquire control of the central microprocessor,

each of said threads having direct access to said program memory address space so as to provide fast efficient preemption of one thread by

another thread and switching of control of the central microprocessor back and forth among the threads at a rate so rapid that the threads execute effectively simultaneously.

Analysis:

Claim 20 is a new claim, which is broader in scope than the original claims. There are four elements missing from the claims (the editor, compiler, interrupt means, and return means). These missing elements are described by applicant as being an essential or critical feature of the claimed invention as a whole as evidenced by applicant's repeated reliance on the presence of these elements throughout the originally filed disclosure. Multiple sections within the application make clear that these four elements served integral functions in the overall invention.

Conclusion:

Reject claim 20 as lacking an adequate written description because four elements described as essential or critical are omitted. The omitted elements are: editor, compiler, interrupt means, and return means.

Example 4 : Original claim

Fact Pattern:

The invention is directed to a form of autopilot, described as a "heading lock," which enables a person to maintain directional control over a watercraft without constant manipulation of trolling motor controls. The preferred embodiment, as set forth in the written description and clearly depicted in detailed drawings, employs a compass mounted to the head of the "heading lock" unit, which monitors the direction of the thrust motor. The heading lock is coupled to the trolling motor; in a preferred embodiment, the heading lock is mechanically coupled to the trolling motor. The disclosure specifically notes that the direction of the thrust motor is considered to be the same as the direction of the boat since the trolling motor is mounted on the bow of the boat. The specification indicates that the electronic steering system continues to monitor the current heading of the thrust and also indicates that the heading detector continuously monitors the current heading of the boat. The term "heading" is used interchangeably throughout the written description to refer to both the direction of the trolling motor and the direction of the boat.

Claim:

1. A heading lock coupled to a trolling motor producing a thrust disposed to pull a watercraft, said heading lock comprising:

a steering motor coupled to said trolling motor, said steering motor being disposed to affect the orientation of said trolling motor in response to input signals;

a steering circuit electrically coupled to said steering motor, said steering circuit being disposed to generate said input signals to said steering motor in response to heading signals; and

a heading detector electrically coupled to said steering circuit, said heading detector being disposed to transmit said heading signals to said steering circuit.

Analysis:

Applicant has identified a heading lock comprising a steering system coupled to a trolling motor and a heading detector, as features essential to the operation of the claimed invention. Although the heading lock is preferably mechanically coupled to the trolling motor, the applicant does not describe the type of coupling as essential to the claimed invention as a whole. A search of the prior art shows that various means for coupling a heading lock to a trolling motor are conventional in the art. The claim is drawn to a single embodiment. Although there is no reduction to practice of the claimed invention, the claimed invention is clearly depicted in detailed drawings.

Conclusion:

The claim is adequately described.

Example 5: Flow Diagrams

Fact Pattern:

The specification is directed to a mechanism for controlling the mode of operation of a modem. A modem is used for modulating and demodulating signals, both analog and digital, over telephone lines. It has two modes: (1) a transparent mode, in which the modem performs the modulation-demodulation function, and (2) a command mode, in which the modem responds to predetermined commands and performs operations by executing a set of instructions stored in Read-Only-Memory (ROM) or firmware. An escape command tells the modem when to switch between transparent and command modes.

The application claims an improved mechanism for detecting an escape command by a modem. The decision making capability and timing means preferably reside in a microprocessor, preferably a Z-8 type microprocessor. The specification discloses logic flow diagrams and provides a detailed functional recitation that describes how to program computers to detect an escape command, but the specification does not provide a computer program listing with source code. The specification describes the escape sequence as one full second of no data, followed by the predetermined escape command, followed by another full second of no data.

Claim:

1. In a modem including a data input port for connecting said modem to a utilization device, and a telephone port for connecting said modem to a

telephone line, said modem being of the type having two distinct modes of operation:

(a) a transparent mode of operation for which said modem provides modulated signals to said telephone port in response to data signals provided to said data input port; and

(b) a command mode of operation for which said modem responds to said data signals provided to said data input port as instructions to said modem;

said modem including means defining a predetermined sequence of said data signals as an escape character; the improvement comprising:

timing means for detecting each occurrence of a passage of a predetermined period of time after provision of one of said data signals to said data input port; and

means, operative when said modem is in said transparent mode of operation, for detecting provision of said predetermined sequence of said data signals, and for causing said modem to switch to said command mode of operation, if and only if said predetermined sequence of data signals occurs contiguous in time with at least one said occurrence of said passage of said predetermined period of time during which none of said data signals are provided to said data input port.

Analysis:

After a review of the full content of the specification, the examiner finds that a modem having two modes of operation (transparent and

command), a timing means, and a means for detecting an escape sequence and causing the modem to switch from the transparent to the command mode are essential to the operation and function of the claimed invention. The specification does not describe a particular timing means or means for detecting the escape command and switching to the command mode. The claim is drawn to a genus. A search of the prior art indicates that the structure of the hardware required is conventional, and that one skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification. A review of the art indicates that there is no substantial variation among the species within the genus. Although no embodiments have been actually reduced to practice, a review of the specification shows that the claimed invention has been reduced to drawings in view of the detailed functional flow diagrams. Since the claimed invention is supported by conventional hardware structure and because there is a functional description of what the software does to operate the computer, there is sufficient description of the claimed invention. Disclosing a microprocessor capable of performing certain functions is sufficient to satisfy the requirement of section 112, first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out.

Conclusion:

The claimed invention has been adequately described.

Biotechnology Examples

Example 6: Genes

Specification: The specification describes an isolated cDNA fragment (SEQ ID NO: 1; a 100mer) obtained from a human glioblastoma cDNA library. SEQ ID NO: 1 is asserted to be homologous to a known DNA molecule that encodes the extracellular domain of a glial specific G-coupled protein receptor whose function is associated with glial cell differentiation. The observed homology is sufficient to support a conclusion that SEQ ID NO: 1 would be glial specific. Further, it would be reasonable to infer that a G-coupled protein receptor encoded by a cDNA that comprised SEQ ID NO: 1 would be involved in the regulation of glial cell differentiation. In the description, applicant defines a "gene" as including naturally occurring regulatory elements and untranslated regions necessary and sufficient to mediate the expression of a cDNA comprising SEQ ID NO: 1. The specification describes methods for cloning nucleic acids that encode full-length glial specific G coupled protein receptors. The specification also discloses that SEQ ID NO: 1 can be used as a probe for identifying the presence of nucleic acids encoding glial specific G-coupled protein receptors in mammals. Glial specific G-coupled protein receptors are disclosed as useful in drug discovery methods to identify agents that regulate glial differentiation. The specification defines a probe as consisting of SEQ ID NO: 1 and between five to 10 additional nucleotides on either end of SEQ ID NO: 1.

Claim:

An isolated gene comprising SEQ ID NO: 1.

Analysis:

A review of the specification indicates that elements which are not particularly described, including regulatory elements and untranslated regions, are essential to the function of the claimed invention because applicant's definition of "gene" requires them. Additionally, SEQ ID NO: 1 is disclosed as being essential to the function of the claimed invention. The art indicates that the structure of genes with naturally occurring regulatory elements and untranslated regions is empirically determined. For example, the structural elements of "gene" mediating the expression of a particular protein in the liver may be different than the structural elements of the "gene" mediating the expression of the same protein in the brain. Therefore the structure of these elements which applicant considers as being essential to the function of the claim are not conventional in the art.

The claim is drawn to a genus, i.e., any gene which comprises SEQ ID NO: 1.

A search of the prior art indicates that SEQ ID NO: 1 is otherwise novel and unobvious, and no associated genomic clones have been identified.

There is no actual reduction to practice of the claimed invention, clear depiction of the claimed invention in the drawings or complete detailed description of the structure.

Considering all disclosed distinguishing identifying characteristics, there is a disclosure of partial structure (SEQ ID NO: 1) as well as the function of the gene as coding for a G-coupled protein receptor.

However, there is no known or disclosed correlation between this function and the structure of the non-described regulatory elements and untranslated regions of the gene. Furthermore, there is no additional disclosure of physical and/or chemical properties. Weighing all factors in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of genes which comprise SEQ ID NO: 1.

Conclusion:

Reject claim 1 under 35 USC 112 first paragraph as lacking an adequate written description. The examiner should make a rejection following a similar type of reasoning as that set forth above.

Note: Applicant may overcome this rejection by claiming a probe which consists essentially of SEQ ID NO: 1, since the specification teaches that a probe can have no more than 10 additional nucleic acid residues at either end of the molecule. The examiner should make an express determination that "consisting essentially of" admits of no more than 10 additional residues at either end of the molecule.

Example 7: EST

Specification: The specification discloses SEQ ID NO: 16 which is a partial cDNA. The specification does not address whether the cDNA crosses an exon/intron splice junction. The specification discloses that this sequence will specifically hybridize with the complement of the coding sequence of a gene of an infectious yeast. The presence of the nucleic acid detected by hybridization with the complement of the coding sequence is useful for identifying yeast infections. Example 1 of the specification describes an experiment where SEQ ID NO: 16 was determined following characterization of a cDNA clone isolated from a cDNA library.

Claim:

An isolated DNA comprising SEQ ID NO: 16.

Analysis:

A review of the full content of the specification indicates SEQ ID NO: 16 is essential to the operation and function of the claimed invention. The specification indicates that the presence of DNA that hybridizes with SEQ ID NO: 16 is indicative of a yeast infection.

A review of the language of the claim indicates that the claim is drawn to a genus, i.e., any nucleic acid that minimally contains SEQ ID NO: 16 within it including any full length gene which contains the sequence, any fusion constructs or cDNAs.

The search indicates that SEQ ID NO: 16 is a novel and unobvious sequence.

There is a single species explicitly disclosed (a molecule consisting of SEQ ID NO: 16 that is within the scope of the claimed genus).

There is actual reduction to practice of the disclosed species.

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses full-length genes and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO: 16 is only a fragment of any full-length gene or cDNA species. When reviewing a claim that encompasses a widely varying genus, the examiner must evaluate any necessary common attributes or features. In the case of a partial cDNA sequence that is claimed with open language (comprising), the genus of, e.g., "A cDNA comprising [a partial sequence]," encompasses a variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its coding region. A partial cDNA that did not include a disclosure of any open reading frame (ORF) of which it would be a part, would not be representative of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule would be disclosed. Further, defining "the" cDNA in functional terms would not suffice in the absence of a disclosure of structural features or elements of a cDNA that would encode a protein having a stated function.

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a

substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Here, the specification discloses only a single common structural feature shared by members of the claimed genus, i.e., SEQ ID NO: 16. Since the claimed genus encompasses genes yet to be discovered, DNA constructs that encode fusion proteins, etc., the disclosed structural feature does not "constitute a substantial portion" of the claimed genus. Therefore, the disclosure of SEQ ID NO: 16 does not provide an adequate description of the claimed genus.

Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO: 16, 2) the breadth of the claim as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs, 3) the lack of correlation between the structure and the function of the genes and/or fusion constructs; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise SEQ ID NO: 16.

Conclusion: The written description requirement is not satisfied.

Caveat: *In situations where the specification indicates that the SEQ ID NO: is a full-length cDNA open reading frame and the claim* ***cannot*** *read on a gene, the claimed invention would meet the written description requirement.*

Example 8: <u>DNA fragment Encoding a Full Open Reading Frame (ORF)</u>

Specification: The specification discloses that a cDNA library was prepared from human kidney epithelial cells and 5000 members of this library were sequenced and open reading frames were identified. The specification discloses a Table that indicates that one member of the library having SEQ ID NO: 2 has a high level of homology to a DNA ligase. The specification teaches that this complete ORF (SEQ ID NO: 2) encodes SEQ ID NO: 3. An alignment of SEQ ID NO: 3 with known amino acid sequences of DNA ligases indicates that there is a high level of sequence conservation between the various known ligases. The overall level of sequence similarity between SEQ ID NO: 3 and the consensus sequence of the known DNA ligases that are presented in the specification reveals a similarity score of 95%. A search of the prior art confirms that SEQ ID NO: 2 has high homology to DNA ligase encoding nucleic acids and that the next highest level of homology is to alpha-actin. However, the latter homology is only 50%. Based on the sequence homologies, the specification asserts that SEQ ID NO: 2 encodes a ligase.

Claim 1: An isolated and purified nucleic acid comprising SEQ ID NO: 2.

Analysis:

A review of the full content of the specification indicates SEQ ID NO: 2 is essential to the operation and function of the claimed invention. The specification indicates that SEQ ID NO: 2 encodes a protein that would be expected to act as a DNA ligase.

A review of the language of the claim indicates that the claim is drawn to a genus, i.e., any nucleic acid that minimally contains SEQ ID NO: 2. The claim is drawn to a nucleic acid comprising a full open reading frame. The claimed nucleic acid does not read on a genomic sequence because full-length mammalian cDNAs would not be expected to contain introns or transcriptional regulatory elements such as promoters that are found in genomic DNA. The claim reads on the claimed ORF in any construct or with additional nucleic acid residues placed at either end of the ORF.

The search indicates that SEQ ID NO: 2 is a novel and unobvious sequence.

There is a single species explicitly disclosed (a molecule consisting of SEQ ID NO: 2 that is within the scope of the claimed genus).

There is actual reduction to practice of the disclosed species.

One of skill in the art can readily envisage nucleic acid sequences which include SEQ ID NO: 2 because e.g. SEQ ID NO: 2 can be readily embedded in known vectors. Although there may be substantial variability among the species of DNAs encompassed within the scope of the claim because SEQ ID NO: 2 may be combined with sequences known in the art,

e.g. expression vectors, the necessary common attribute is the ORF (SEQ ID NO: 2).

Weighing all factors including (1) that the full length ORF (SEQ ID NO: 2) is disclosed and (2) that any substantial variability within the genus arises due to addition of elements that are not part of the inventor's particular contribution, taken in view of the level of knowledge and skill in the art, one skilled in the art would recognize from the disclosure that the applicant was in possession of the genus of DNAs that comprise SEQ ID NO: 2.

Conclusion: The written description requirement is satisfied.

Example 9: Hybridization

Specification: The specification discloses a single cDNA (SEQ ID NO:1) which encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity. The specification includes an example wherein the complement of SEQ ID NO: 1 was used under highly stringent hybridization conditions (6XSSC and 65 degrees Celsius) for the isolation of nucleic acids that encode proteins that bind to dopamine receptor and stimulate adenylate cyclase activity. The hybridizing nucleic acids were not sequenced. They were expressed and several were shown to encode proteins that bind to a dopamine receptor and stimulate adenylate cyclase activity. These sequences may or may not be the same as SEQ ID NO: 1.

Claim:

An isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1,

wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity.

Analysis:

A review of the full content of the specification indicates that the essential feature of the claimed invention is the isolated nucleic acid that hybridizes to SEQ ID NO: 1 under highly stringent conditions and encodes a protein with a specific function. The art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing.

The claim is drawn to a genus of nucleic acids all of which must hybridize with SEQ ID NO: 1 and must encode a protein with a specific activity.

The search of the prior art indicates that SEQ ID NO: 1 is novel and unobvious.

There is a single species disclosed (a molecule consisting of SEQ ID NO: 1) that is within the scope of the claimed genus.

There is actual reduction to practice of the disclosed species.

Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of

skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.

Conclusion: The claimed invention is adequately described.

Example 10: Process claim

Specification: The specification teaches that SEQ ID NO: 10 is an EST. The specification also teaches that SEQ ID NO: 10 is a chromosome marker and that any DNA which hybridizes under specified stringent conditions to SEQ ID NO: 10 will be useful as a marker for detecting the presence of Burkitt's lymphoma. The specification also teaches how to produce DNAs including genomic DNAs which hybridize to SEQ ID NO: 10 and isolation of said DNAs. The specification presents an example where a genomic DNA is probed with SEQ ID NO: 10 under the specified stringent conditions (6XSSC and 65 degrees Celsius) and the genomic DNA which hybridizes under these conditions is isolated and is sequenced. The sequence of this genomic clone is represented by SEQ ID NO: 11.

Claim:

Claim 1: A process for producing an isolated polynucleotide comprising hybridizing SEQ ID NO: 10 to genomic DNA in 6XSSC and 65° C and isolating the DNA polynucleotide detected with SEQ ID NO: 10.

Claim 2: An isolated DNA that hybridizes with SEQ ID NO: 10.

Analysis:

Claim 1:

A review of the full content of the specification indicates that the essential feature of the claimed invention is a process of obtaining a nucleic acid sequence which is identified by a probe that hybridizes to SEQ ID NO:10 and a polynucleotide that hybridizes with SEQ ID NO: 10. The

specification and the general state of the art indicate that the general process of producing nucleic acids through hybridization with probes was routine at the time of filing.

The claim is drawn to a genus i.e., a process of hybridizing to genomic DNA with SEQ ID NO: 10 and isolating the DNA which hybridizes under specific conditions to said sequence.

The search indicates that SEQ ID NO: 10 and SEQ ID NO: 11 are novel and unobvious sequences. Therefore, under the examination guidelines of *In re Ochiai* and *In re Brouwer*, the method of making a novel and unobvious product is also novel and unobvious.

The specification presents an example where a single species has been reduced to practice, i.e., isolation of SEQ ID NO: 11 based on hybridization with SEQ ID NO: 10. Therefore the disclosed species within the genus has been adequately described. Now turning to the genus analysis, the art indicates that there is no substantial variation within the genus because of the stringency of hybridization conditions which yields structurally similar molecules. The single disclosed species is representative of the genus because reduction to practice of this species, considered along with the defined hybridization conditions and the level of skill and knowledge in the art, are sufficient to allow the skilled artisan to recognize that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus.

Claim 2:

The claim is drawn to a genus of nucleic acids, all of which must hybridize to SEQ ID NO: 10. The claim does not specify any stringency conditions. The claim is broad and reads on virtually any nucleic acid.

There is a species disclosed, SEQ ID NO: 11. The art indicates that there is substantial variation within the genus because the lack of stringency of hybridization conditions would be expected to yield structurally unrelated nucleic acid molecules. The single disclosed species is not representative of the genus because there is no structural attribute or feature that is common to the members of the genus.

Conclusion:

Claim 1 is adequately described.

Claim 2 should be rejected as lacking adequate written description following the analysis described above.

Note: Applicant may overcome the written description rejection of the product by, for example, substituting claim 2 with a product by process claim such as the one below.

Claim 2. *The isolated DNA polynucleotide prepared according to the process of claim 1.*

Example 11: Allelic Variants

Specification: The specification discloses a DNA, SEQ ID NO: 1, said to encode a cell surface receptor for adenovirus. The cell surface receptor is designated protein X and its sequence is given as SEQ ID NO:2. The specification states that the invention includes alleles of the DNA that include single nucleotide polymorphisms (SNPs). No allelic sequence information is disclosed, but the specification states that allelic variants of SEQ ID NO: 1 can be obtained, e.g., by hybridizing SEQ ID NO: 1 to a DNA library made from the species of organism that yielded SEQ ID NO: 1.

Claims:

1. An isolated DNA that encodes protein X (SEQ ID NO: 2).

2. An isolated allele of the DNA according to claim 1, which allele encodes protein X (SEQ ID NO: 2).

3. An isolated allele of SEQ ID NO: 1.

Analysis:

Claim 1:

Claim 1 is drawn to the genus of DNAs that encode amino acid sequence SEQ ID NO:2, i.e., all sequences degenerately related by a genetic code table to SEQ ID NO:1. Although only one specie within the genus is disclosed, SEQ ID NO:1, a person of skill in the art could readily envision all the DNAs degenerate to SEQ ID NO:1 by using a genetic code table. One of skill in the art would conclude that applicant was in possession of the

genus based on the specification and the general knowledge in the art concerning a genetic coding table.

Claim 2:

Claim 2 is drawn to a subgenus of allelic DNAs that encode amino acid sequence SEQ ID NO: 2. The specification does not provide any particular definition for the term allele. In this circumstance, the meaning of the term is the ordinary usage in the art. The ordinary meaning of the term allele is one of two or more alternate forms of a gene occupying the same locus in a particular chromosome or linkage structure and differing from other alleles of the locus at one or more mutational sites. See, Rieger et al., *Glossary of Genetics* (1991), p. 16. The alleles in claim 2 are "strictly neutral" because they encode identical proteins, and make no difference to phenotype. See, Rieger et al., p. 17. Although the standard definition refers to genomic sequences and the claims are directed to DNAs, a reasonable interpretation is that the claim is directed to DNAs that include naturally occurring mutational site(s).

The specification discloses only one allele within the scope of the genus: SEQ ID NO:1. The specification proposes to discover other members of the genus by using a hybridization procedure. There is no description of the mutational sites that exist in nature, and there is no description of how the structure of SEQ ID NO: 1 relates to the structure of any strictly neutral alleles. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that they are variant structures, and in the present state of the art the structure of one does

not provide guidance to the structure of others. The common attributes of the genus are not described. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

Claim 3:

Claim 3 is drawn to the genus including all DNA alleles of SEQ ID NO: 1. The specification does not provide any particular definition for the term allele. In this circumstance, the meaning of the term is the ordinary usage in the art. The ordinary meaning of the term allele is one of two or more alternate forms of a gene occupying the same locus in a particular chromosome or linkage structure and differing from other alleles of the locus at one or more mutational sites. See, Rieger et al., *Glossary of Genetics* (1991), p. 16. The Rieger reference discloses that there are at least seven different kinds of allele in addition to the "strictly neutral" type discussed above for Claim 2. See, Rieger, pp. 16-17 (amorphs, hypomorphs, hypermorphs, antimorphs, neomorphs, isoalleles, and unstable alleles). The alleles are distinguished by the effect their different structures have on phenotype. According to Rieger, alleles may differ functionally according to their distinct structures. For example, they may differ in the amount of biological activity the protein product may have, may differ in the amount of protein produced, and may even differ in the kind of activity the protein product will have.

The specification discloses only one allele within the scope of the genus: SEQ ID NO:1. The specification proposes to discover other

members of the genus by using a hybridization procedure. There is no description of the mutational sites that exist in nature, and there is no description of how the structure of SEQ ID NO: 1 relates to the structure of different alleles. In addition, according to the standard definition, the genus includes members that would be expected to have widely divergent functional properties. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of other unknown alleles having concordant or discordant functions. The common attributes of the genus are not described and the identifying attributes of individual alleles, other than SEQ ID NO:1, are not described. The nature of alleles is that they are variant structures where the structure and function of one does not provide guidance to the structure and function of others. According to these facts, one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

Conclusions:

Claim 1:

Claim 1 should not be rejected under the written description requirement.

Claim 2:

Claim 2 should be rejected under the written description requirement. An analysis similar to the one set forth above could be used. Since the Office has the burden of presenting evidence to support its position, see

MPEP 2163.04, a reference should be relied on as authority for the Office's interpretation of the claim term "allele."

Claim 3:

Claim 3 should be rejected under the written description requirement. An analysis similar to the one set forth above could be used. Since the Office has the burden of presenting evidence to support its position, see MPEP 2163.04, a reference should be relied on as authority for the Office's interpretation of the claim term "allele."

For the rejections of claims 2 and 3, the Office interpretation of "allele" should be supported by a reference, rather than by taking "notice," because the interpretation is the principle evidence supporting the rejection. See MPEP 2144.03 (For further views on official notice, see *In re Ahlert*, 424 F.2d 1088, 1091 165 USPQ 418, 420 - 421 (CCPA 1970) ("[A]ssertions of technical facts in areas of esoteric technology must always be supported by citation of some reference work" and "allegations concerning specific `knowledge' of the prior art, which might be peculiar to a particular art should also be supported." Furthermore the applicant must be given the opportunity to challenge the correctness of such assertions and allegations. "The facts so noticed serve to `fill the gaps' which might exist in the evidentiary showing" and should not comprise the principle evidence upon which a rejection is based.); see also, *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971) (scientific journal references were not used as a basis for taking judicial notice that controverted phrases were art - recognized because the court was not sure that the meaning of the term at issue was indisputable among reasonable men); *In re Eynde*, 480 F.2d 470, 178 USPQ

470,474 (CCPA 1973) ("The facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men and are not amenable to the taking of [judicial] notice.").)

Example 12: Bioinformatics

Specification: The specification discloses a process for identifying and selecting biological compounds that are present in a biological system in a tissue specific manner. In the disclosed process the expression level of a set of compounds is quantitatively determined in multiple tissues within an organism. The expression level data is then graphically displayed in such a manner that compounds that are differentially expressed are easily identified. An artisan interested in identifying a compound that is expressed at a high level in one tissue and at a different level in a second tissue may easily select compounds that are expressed in a tissue specific manner based on the displayed information. The specification indicates that the compounds to be detected encompass DNA, RNA and proteins as well as metabolites. The specification does not provide any particular examples, but discloses that the expression levels can be determined by any analytical method consistent with the class of compounds being detected. This type of measurement requires actual physical steps.

Claim:

A computer-implemented method of selecting tissue specific compounds, said method comprising the steps of:

(a) analyzing the expression level of compounds in a first and second tissue and obtaining expression level data for each of said compounds;

(b) inputting the expression level data obtained in step a) into a computer;

(c) displaying a first axis corresponding to the expression level of each of said compounds in said first tissue;

(d) displaying a second axis substantially perpendicular to said first axis, said second axis corresponding to the expression level data of each of said compound in said second sample

(e) displaying a mark at a position, wherein said position is selected relative to said first axis in accordance with an expression level of each of said compound in said first sample and relative to said second axis in accordance with the expression of said compound in said second sample; and

(f) selecting a compound of interest based on the position of the mark.

Analysis:

A review of the full content of the specification indicates that obtaining, inputting, and displaying the expression level of compounds is essential to the operation of the claimed invention.

A search of the prior art indicates that obtaining the expression level data of compounds is conventional in the art, and that data display devices and associated support algorithms are well known in the art.

A review of the claim indicates that the claim is drawn to a generic environment for the display of compounds in a tissue specific manner.

Since there is no species claimed or disclosed, the claim is analyzed as a claim drawn to a single embodiment. There is no actual reduction to practice of the claimed invention, or clear depiction of the claimed invention

in detailed drawings. However, reading the specification in light of the knowledge and level of skill in the art, the specification discloses the complete steps of the claimed process. See In re Hayes Microcomputer Products Inc. Patent Litigation, 982 F2d. 1527, 1534-35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992), where the court stated,

> One skilled in the art would know how to program a microprocessor to perform the necessary steps desired in the specification. Thus, an inventor is not required to describe every detail of his invention. An applicant's disclosure obligation varies according to the art to which the invention pertains.

In this fact situation, the art is sufficiently developed so as to put one of skill in the art in possession of the complete steps of the process. In other words, one skilled in the relevant art would understand what is intended by the claimed invention and know how to carry it out.

Conclusion: There is adequate written description for what is claimed.

Example 13: Protein Variant

Specification: The specification describes a protein isolated from liver. A working example shows that the isolated protein was sequenced and determined to consist of SEQ ID NO: 3. The isolated protein was additionally characterized as being 65 kD in molecular weight and having tumor necrosis activity. The specification states that the invention provides variants of SEQ ID NO: 3 having one or more amino acid substitutions, deletions, insertions and/or additions. No further description of the variants is provided. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and/or additions are routine in the art. The specification does not define when a protein ceases to be a variant of SEQ ID NO: 3.

Claims:

1. An isolated protein having SEQ ID NO: 3.

2. An isolated variant of the protein of claim 1.

Analysis:

Claim 1:

A search of the prior art indicates that SEQ ID NO: 3 is novel and nonobvious. The claim is directed to a genus of proteins that comprise SEQ ID NO: 3. One member of the genus, SEQ ID NO: 3, is described by a complete structure.

There is relatively little variation among the species within the genus because each member of the genus shares SEQ ID NO: 3 as a necessary common feature. The single disclosed example is representative of the claimed genus because taken in view of the general knowledge in the art, the disclosure is sufficient to show that one of skill in the art would conclude that applicant was in possession of the claimed genus.

Claim 2:

This is a genus claim. According to the specification, the term variant means a protein having one or more amino acid substitutions, deletions, insertions and/or additions made to SEQ ID NO: 3. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to SEQ ID NO: 3. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the art, the specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 3 alone is insufficient to

describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Conclusions:

Claim 1:

The claimed subject matter is adequately described. A rejection under the written description requirement should not be entered.

Claim 2:

The claimed subject matter is not supported by an adequate written description because a representative number of species have not been described. A rejection under the written description requirement, relying on the analysis set out above, should be entered.

Example 14: Product by Function

Specification: The specification exemplifies a protein isolated from liver that catalyzes the reaction of A $\longrightarrow$ B. The isolated protein was sequenced and was determined to have the sequence as set forth in SEQ ID NO: 3. The specification also contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and additions is routine in the art and provides an assay for detecting the catalytic activity of the protein.

Claim:

A protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction of A $\longrightarrow$ B.

Analysis:

A review of the full content of the specification indicates that a protein having SEQ ID NO: 3 or variants having 95% identity to SEQ ID NO: 3 and having catalytic activity are essential to the operation of the claimed invention. The procedures for making variants of SEQ ID NO: 3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO: 3 which have 95% identity to SEQ ID NO: 3 and retain its activity are conventional in the art.

A review of the claim indicates that variants of SEQ ID NO: 3 include but are not limited to those variants of SEQ ID NO: 3 with substitutions, deletions, insertions and additions; but all variants must possess the specified catalytic activity and must have at least 95% identity to the SEQ ID NO: 3. Additionally, the claim is drawn to a protein which **comprises** SEQ ID NO: 3 or a variant thereof that has 95% identity to SEQ ID NO: 3. In other words, the protein claimed may be larger than SEQ ID NO: 3 or its variant with 95% identity to SEQ ID NO: 3. It should be noted that "having" is open language, equivalent to "comprising".

The claim has two different generic embodiments, the first being a protein which comprises SEQ ID NO: 3 and the second being variants of SEQ ID NO: 3. There is a single species disclosed, that species being SEQ ID NO: 3.

A search of the prior art indicates that SEQ ID NO: 3 is novel and unobvious.

There is actual reduction to practice of the single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO: 3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO: 3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO: 3 which are capable of the specified catalytic activity. One of skill in the art would conclude that

applicant was in possession of the necessary common attributes possessed by the members of the genus.

Conclusion: The disclosure meets the requirements of 35 USC §112 first paragraph as providing adequate written description for the claimed invention.

Example 15: Antisense

Specification: The specification discloses a messenger RNA sequence, SEQ ID NO: 1, which encodes human growth hormone. The specification states that the invention includes antisense molecules that inhibit the production of human growth hormone. The specification describes an art-recognized method of screening for antisense molecules that is called "gene walking." Gene walking is said to involve obtaining antisense oligonucleotides that are complementary to the target sequence.

Claim:

An antisense oligonucleotide complementary to a messenger RNA having SEQ ID NO: 1 and encoding human growth hormone, wherein said oligonucleotide inhibits the production of human growth hormone.

Analysis:

A review of the full content of the specification indicates that the complement of SEQ ID NO: 1 is essential to the operation of the claimed invention. The general knowledge in the art is that any full-length complement of a target mRNA inhibits the function of the mRNA and is therefore an antisense oligonucleotide. Thus, one of skill in the art would view applicant's disclosure of a coding sequence, with the statement that the invention includes antisense oligonucleotides, as an implicit disclosure that the full-length complement of SEQ ID NO: 1 is an antisense oligonucleotide.

It is generally accepted in the art that oligonucleotides complementary to a messenger RNA, including fragments of the full-length complement, have antisense activity when they match accessible regions on the target mRNA. Generally, the closer the complementary fragment is to full length, the greater the likelihood it will have antisense activity. In addition, oligos that retain complementarity to the Shine-Delgarno sequence usually have antisense activity.

The claim is drawn to the genus of antisense molecules that inhibit the production of human growth hormone encoded by SEQ ID NO: 1. There is a single species described with a complete structure, i.e., the full-length complement of SEQ ID NO: 1. In addition to the full-length complement, the genus includes fragments of the complement that retain antisense activity.

The procedures for making oligonucleotide fragments of the SEQ ID NO: 1 complement are conventional, e.g., any specified fragment can be ordered from a commercial synthesizing service. The procedures for screening for antisense activity are also conventional, and the specification describes the assay needed to do gene walking. The experience accumulated in the art with gene walking is that numerous regions of a target are accessible, that these regions are identified routinely, and that antisense oligonucleotides are complementary to these accessible regions. The full-length complement and longer fragments match multiple accessible regions; shorter fragments match fewer accessible regions.

When considering the distinguishing characteristics of the claimed invention, the sequence provided in the specification defines and limits the

structure of any effective antisense molecules. The specification also teaches the functional characteristics of the claimed invention as well as a routine art recognized method of making and screening for the claimed invention. Considering the specification's disclosure of:

(1) the sequence (SEQ ID NO: 1) which defines and limits the structure of any effective antisense molecules such that one skilled in the art would be able to immediately envisage members of the genus embraced by the claim, and

(2) the functional characteristics of the claimed invention as well as a routine art-recognized method of screening for antisense molecules which provide further distinguishing characteristics of the claimed invention, along with

(3) the general level of knowledge and skill in the art,

one skilled in the art would conclude that applicant was in possession of the invention.

Conclusion: The claimed invention is adequately described.

Example 16: Antibodies

Specification: The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

Claim: An isolated antibody capable of binding to antigen X.

Analysis:

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

A search of the prior art indicates that antigen X is novel and unobvious.

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.

Conclusion: The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.

Example 17: Genus-species with widely varying species

Specification: The specification discloses the rat cDNA sequences for proinsulin and pre-proinsulin and a method for determining the corresponding human and other mammalian insulin cDNA sequences. However, the specification does not disclose any actual cDNA sequence other than the rat proinsulin and pre-proinsulin sequence. The specification discloses that one human proinsulin amino acid (but not cDNA) sequence was known at the time of filing. The art recognized that the sequence of human insulin proteins, and therefore also cDNAs, would probably vary among individuals. The specification also discloses that pre-proinsulin is post translationally modified to form proinsulin, and that proinsulin is cleaved to form insulin.

Claims:

Claim 1. An isolated mammalian cDNA encoding insulin.

Claim 2. The isolated cDNA of claim 1 wherein the mammalian cDNA is human.

Analysis: The examiner should analyze claim 2 first because it is drawn to a subgenus of the genus of claim 1.

Claim 2:

A review of the full content of the specification indicates that human cDNA molecules that encode insulin are essential to the operation/function of the invention.

Claim 2 is directed to a genus of human cDNA which encodes insulin.

There is no species of human insulin cDNA disclosed.

Based upon art published after applicant's filing date there is expected to be variation among the species of cDNA which encode human insulin because the sequence of human insulin proteins, and therefore also human insulin cDNAs, would be expected to vary among individuals.

The specification discloses only the sequence of a single human proinsulin protein, and does not disclose any human cDNA sequence at all.

In addition, there is no evidence on the record of a relationship between the structure of rat insulin cDNA and the structure of insulin cDNAs from humans or other mammals that would provide any reliable information about the structure of other insulin cDNAs on the basis of the rat insulin cDNA.

There is no evidence on the record that the disclosed rat cDNA proinsulin sequence had a known structural relationship to the human cDNA sequence, or to other mammalian cDNA sequences; the specification discloses only a single human proinsulin (protein) sequence; the art indicated that human proinsulin proteins were expected to be variable in structure; and there is expected to be variation among human cDNAs that

encode a given human proinsulin. In view of the these considerations, a person of skill in the art would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed human cDNA.

Claim 1:

Claim 1 is directed to a genus of mammalian cDNAs which encode insulin. The specification evidences actual reduction to practice of the rat cDNA sequences for proinsulin and preproinsulin, but does not disclose any other cDNA sequences. The art indicates that there is likely to be substantial variation among the species within the genus of cDNAs that encode mammalian insulins because the sequences of the mammalian insulin proteins, and therefore the mammalian cDNAs, would be expected to vary among species.

The specification discloses a method for determining the corresponding human and other mammalian insulin cDNA sequences as well as the function of the claimed sequences. However, neither the specification nor the general knowledge of those skilled in the art provide evidence of any partial structure which would be expected to be common to the members of the genus. Moreover, there is post filing date evidence that indicates that there is a lack of a structural relationship between the rat insulin cDNA sequences and other mammalian insulin cDNA sequences. In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by members of the genus, because rat cDNA sequences are not representative of the claimed genus. Consequently, since applicant was in

possession only of the rat insulin cDNA and since the art recognized variation among the species of the genus of cDNAs that encode mammalian insulin, the rat insulin cDNA was not representative of the claimed genus. Therefore, the applicant was not in possession of the genus of mammalian insulin cDNAs as encompassed by claim 1.

Conclusion:

Claims 1 and 2 do not meet the written description requirement.

Example 18: <u>Process claim where the novelty is in the method steps.</u>

Specification: The specification teaches a method for producing proteins using mitochondria from the fungus *Neurospora crassa*. In the method, mitochondria are isolated from this fungus and transformed with a mitochondrial expression vector which comprises a nucleic acid encoding a protein of interest. The protein is subsequently expressed, the mitochondria is lysed, and the protein is isolated. The specification exemplifies the expression of β-galactosidase using the claimed method using a cytochrome oxidase promoter.

Claim:

1. A method of producing a protein of interest comprising;

obtaining *Neurospora crassa* mitochondria,

transforming said mitochondria with a expression vector comprising a nucleic acid that encodes said protein of interest,

expressing said protein in said mitochondria, and

recovering said protein of interest.

Analysis:

A review of the specification reveals that *Neurospora crassa* mitochondrial gene expression is essential to the function/operation of the claimed invention. A particular nucleic acid is not essential to the claimed invention.

A search of the prior art reveals that the claimed method of expression in *Neurospora crassa* is novel and unobvious.

The claim is drawn to a genus, i.e., any of a variety of methods that can be used for expressing protein in the mitochondria.

There is actual reduction to practice of a single embodiment, i.e., the expression of β-galactosidase.

The art indicates that there is no substantial variation within the genus because there are a limited number of ways to practice the process steps of the claimed invention.

The single embodiment is representative of the genus based on the disclosure of *Neurospora crassa* mitochondria as a gene expression system, considered along with the level of skill and knowledge in the gene expression art. One of skill in the art would recognize that applicant was in possession of all of the various expression methods necessary to practice the claimed invention.

Conclusion:

The claimed invention is adequately described.

APPENDIX 'E'

lers's argument that various policy exclusions preclude Frog's suit. Finally, we reject in the margin Frog's claim for bad faith denial of coverage. The Orders of the District Court will be affirmed.

ever, would be limited to the harm caused by the advertisement.

At all events, the belt-and-suspenders approach to denying coverage is, in this case, unnecessary. Causation alone does not equate to insurance coverage. Perhaps courts have failed to engage in rigorous causation analysis in many cases because they have already found that there is no advertising injury. Indeed, we have found no actual case in which a court has found "advertising injury" but not causation. *Cf. International Communication Materials, Inc. v. Employer's Ins.*, No. 94-1789, 1996 U.S. Dist. LEXIS 21825 (W.D. Pa. May 29, 1996) (finding that, where the policy listed patent infringement under the definition of "advertising injury," there was a genuine issue of material fact regarding whether the infringement caused harm in the course of advertising). While Amsco's underlying complaint specifically alleges that Frog's advertising contributed to its injuries, thus sufficiently alleging a causal connection between the advertising and the injury, that is not enough to trigger the insurers' duty to defend.

A refusal, with no good cause, to provide a defense or to indemnify when the policy provides for coverage violates Pennsylvania's bad faith insurance statute. *See* 42 Pa. Stat. Ann. §8371 (creating a remedy "if the court finds that the insurer has acted in bad faith towards the insured"). Bad faith is a frivolous or unfounded refusal to pay, lack of investigation into the facts, or a failure to communicate with the insured. *See Coyne v. Allstate Ins. Co.*, 771 F.Supp. 673, 678 (E.D. Pa. 1991) (bad faith is failure to acknowledge or act promptly on the claims, or refusing to pay without reasonable investigation of all available information); *Romano v. Nationwide Mut. Fire Ins. Co.*, 646 A.2d 1228 (Pa. Super. Ct. 1994). Good faith is no defense if there was in fact no good cause to refuse coverage. *See Gedean v. State Farm Mut. Auto. Ins. Co.*, 188 A.2d 320, 322 n.4 (Pa. 1963). However, mere negligence or bad judgment does not constitute bad faith; knowledge or reckless disregard of a lack of a basis for denial of coverage is necessary. *Winner International Corp. v. Continental Casualty Co.*, 889 F.Supp. 809 (W.D. Pa. 1994), *aff'd without opinion*, 54 F.3d 767 (3d Cir. 1995).

The District Court reasoned that bad faith claims cannot survive a determination that there was no duty to defend, because the court's determination that there was no potential coverage means that the insurer had good cause to refuse to defend. *See Lucker Mfg. v. Home Ins. Co.*, 23 F.3d 808, 821 n. 19 (3d Cir. 1994); *Hyde Ath. Indus., Inc. v. Continental Cas. Co.*, 969 F.Supp. 289, 306 (E.D. Pa. 1997).

Frog argues that a bad faith claim is not contingent on success on the underlying breach of contract claim, citing *Doylestown Electric Supply Co. v. Maryland Casualty Insurance Co.*, 942 F.Supp. 1018, 1020 (E.D. Pa. 1996). But that case involved a situation in which the statute of limitations had expired on the breach of contract claim; a breach of a duty to defend was unredressable for procedural reasons, but it was still possible that a bad faith claim could succeed. Here, where there was no duty to defend, there was good cause to refuse to defend against a suit.

U.S. Court of Appeals
Federal Circuit

Tec Air, Inc. v. Denso Manufacturing Michigan Inc.

No. 99-1011

Decided September 30, 1999

PATENTS

1. Patentability/Validity — Anticipation — Prior sale — Degree of development (§115.0707.05)

Reasonable jury could have found that infringement plaintiff's offers to sell fan blades did not raise on-sale bar of 35 U.S.C. §102(b), since evidence supports finding that subject matter of offers does not fully anticipate claimed invention, and since defendant does not argue that it would have rendered invention of patents in suit obvious; whether invention was ready for patenting at time of offers is irrelevant under these circumstances, since subject matter of commercial offer for sale must "be something within the scope of the claim."

2. Patentability/Validity — Obviousness — Combining references (§115.0905)

Reasonable jury could have found that invention of patents for apparatus and method of molding plastic fan blades was not obvious in view of prior art patent and method in combination, since combination would be inoperable for its intended purpose, and since jury reasonably could have found that prior patent taught away from its combination with prior art method.

3. Patentability/Validity — Obviousness — Secondary considerations generally (§115.0907)

Plaintiff presented sufficient objective evidence to rebut any showing that invention of patents for apparatus and method of molding plastic fan blades was obvious, since evidence showed that millions of fan blades made using patented method were sold, since these sales figures, even without market share data, constitute evidence of commercial success, since evidence shows nexus between sales and patented invention, and since plaintiff offered evidence that invention satisfied long-felt but unmet need.

REMEDIES

4. Monetary — Damages — Patents — Reasonable royalty (§510.0507.03)

Jury properly applied "entire market value" rule in awarding damages to plaintiff for defendant's infringement of patents for apparatus and method of molding plastic fan blades, since evidence shows that defendant did not sell its radiator and condenser assemblies without fans, that performance and price of entire system were of paramount importance to its customers, that customers wanted fans balanced to certain specification, and that defendant could not meet that specification after abandoning patented method, and since from this evidence, jury could have reasonably concluded that demand for entire assembly depended upon patented invention.

Particular patents — General and mechanical — Fans and blowers

4,047,692, Swin, apparatus for molding dynamically balanced fans, judgment that patent is not invalid affirmed.

4,107,257, Swin, method for molding dynamically balanced fans, judgment that patent is not invalid affirmed.

Appeal from the U.S. District Court for the Northern District of Illinois, Manning, J.

Action by Tec Air Inc. against Denso Manufacturing Michigan Inc., f/k/a Nippondenso Manufacturing USA Inc., and Denso Corp., k/k/a Nippondenso Co. Ltd., for patent infringement. Defendant appeals from denial of its motion for judgment as matter of law, or for new trial, on issues of patent validity and damages. Affirmed.

Related decision: 49 USPQ2d 1944.

Jerold A. Jacover, Richard A. Kaplan, Rodney A. Daniel, Bradley G. Lane, and James M. McCarthy, of Brinks, Hofer, Gilson & Lione, Chicago, Ill., for plaintiff-appellee.

William A. Streff, Jr., of Kirkland & Ellis, Chicago; Paul R. Steadman and Jay I. Alexander, of Kirkland & Ellis, Washington, D.C.; Kenneth J. Jurek, and Rosanne J. Faraci, of McDermott, Will & Emery, Chicago, for defendants-appellants.

Before Mayer, chief judge, and Michel and Lourie, circuit judges.

Mayer, C.J.

Denso Manufacturing Michigan, Inc. and Denso Corporation (collectively "Denso") appeal the September 24, 1998 judgment of the United States District Court for the Northern District of Illinois, No. 91-CV-4488, which was entered after the court denied Denso's motion for judgment as a matter of law, or alternatively, for a new trial on the issues of patent validity and damages. We affirm.

Background

Tec Air, Inc. ("Tec Air") owns U.S. Patent Nos. 4,047,692 and 4,107,257 ("the Swin patents"), both of which have effective filing dates of September 24, 1975. The Swin patents describe a method of and a device for making properly balanced, injected-molded fans. One way to balance a plastic fan is to use balance "pads," "lugs," or "plugs," which are deposits of plastic located in appropriate places on the fan. To create these lugs, a hollow column is formed in a steel fan mold, which fills with molten plastic during the injection-molding process. When Tec Air entered the fan molding business in 1972, like other manufacturers, it used several methods of creating these columns, such as grinding or drilling holes in mold inserts and refilling them if needed. A mold insert forms a portion of the overall fan. Tec Air also inserted replaceable brass rods into hollowed-out sections of the mold insert, which are drilled more easily because brass is a softer metal than steel (the "brass plug method"). In June 1974, Tec Air's employee, Richard Swin, Sr., conceived the method disclosed in the Swin patents—inserting adjustable screws into hollowed-out sections of the mold insert that is used to form the fan hub. These screws are accessible from the front or cavity-side of the mold.

Throughout the development of the claimed invention, Tec Air continued to market its fans and fan molds. For example, in June 1974, Tec Air offered to sell Keeprite Products ("Keeprite") injected-molded fans and the corresponding mold. Keeprite placed an order in July 1974 and Tec Air created drawings for the Keeprite fan. One drawing, dated August 16, 1974, shows "balance plugs" on the fan, but does not specify the method of creating them. Before September 24, 1974, Tec Air asked its mold maker, Jack Dearhammer at Mid City Tool & Die, to

quote it a price for making a mold insert for the Keeprite fan. The sketch used for this price quotation did not show balance plugs, but Dearhammer ultimately made the mold insert capable of producing balance plugs by inserting adjustable screws into hollowed-out sections of the mold. In another attempt to solicit business, Tec Air sent sample fans to Howard Industries on August 14, 1974. These fans were model number 4B-60-21. On August 13, 1974, Dearhammer returned to Tec Air the mold insert used to make the 4B-60-21 fan, after he had modified it to include the patented invention's adjustable screws. Prior to sending the mold to Dearhammer, however, Tec Air accumulated thousands of the 4B-60-21 fans in its inventory, which were made by prior art balancing techniques.

In 1991, Tec Air sued Denso for infringement because it manufactured radiator and condenser assemblies that included a fan that was balanced according to the claimed method. Tec Air won the infringement phase of the trifurcated trial, which Denso does not appeal. A jury then heard the invalidity phase of the suit, in which Denso argued that the patents are invalid because Tec Air offered the invention for sale more than one year before the effective filing date and because the invention of the claims would have been obvious. The jury returned special interrogatories indicating that Tec Air neither sold nor offered the invention for sale before the critical date and that the patented invention would not have been obvious. The same jury subsequently awarded damages of $25.2 million, which corresponds to a royalty of 6.5% of the infringing sales of Denso's entire radiator and condenser assemblies, but is nevertheless less than the royalty requested by Tec Air. Denso moved for judgment as a matter of law, or alternatively, for a new trial on the validity and damages issues.

The court denied the motion for judgment as a matter of law because, although the evidence showed that Tec Air possessed mold inserts having adjustable screws before the critical date, there was evidence that Tec Air did not use these inserts to create commercial products. In addition, the court determined not only that Denso failed to establish a *prima facie* case of obviousness for lack of a suggestion to combine the cited references, but also that Tec Air produced sufficient objective evidence of nonobviousness. The court also held that the jury properly used the entire market value rule in measuring damages because each Denso assembly was a single functioning unit, which included the infringing fan. The court then denied Denso's motion for a new trial because the evidence was sufficient to support the invalidity verdict and the damage award was neither excessive nor the product of improper considerations. This appeal followed.

Discussion

"We review a trial court's decision on a motion for judgment as a matter of law following a jury verdict by reapplying its own standard of review. Therefore, for [Denso] to prevail on appeal it must prove that the jury's factual findings were not supported by substantial evidence or that the facts were not sufficient to support the conclusions necessarily drawn by the jury on the way to its verdict." *Applied Med. Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1376, 47 USPQ2d 1289, 1290 (Fed. Cir. 1998) (citations omitted). In evaluating whether Denso met this standard, "we must consider the evidence of record in the light most favorable to [Tec Air], drawing all reasonable inferences in its favor, without disturbing the jury's credibility determinations or substituting our resolutions of conflicting evidence for those of the jury." *Id.* at 1376-77, 47 USPQ2d at 1291. If no reasonable person could have reached a verdict for Tec Air in light of the record before the jury, Denso will prevail. *See id.* at 1376, 47 USPQ2d at 1291.

On-Sale Bar

"The ultimate determination that a product was placed on sale under [35 U.S.C. § 102(b) (1994)] is a question of law, based on underlying facts." *Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1566, 33 USPQ2d 1512, 1514-15 (Fed. Cir. 1995). To prove that the Swin patents are invalid for violating the on-sale bar, Denso "must demonstrate by clear and convincing evidence that there was a definite sale or offer to sell more than one year before the application for the subject patent, and that the subject matter of the sale or offer to sell fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art." *Id.* (internal quotations omitted); *see also Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 119 S.Ct. 304, 311, 48 USPQ2d 1641, 1647 (1998) ("First, the product must be the subject of a commercial offer for sale."); *Scaltech Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1383, 51 USPQ2d 1055, 1058 (Fed. Cir. 1999) ("[T]he first determination in the § 102(b) analysis must be whether the subject of the barring activity

met each of the limitations of the claim, and thus was an embodiment of the claimed invention."). If this subject matter anticipates the claimed invention or would have rendered it obvious, the invention itself must also have been "ready for patenting" at the time of the offer or sale—e.g., the invention must have been reduced to practice or embodied in "drawings or other descriptions . . . that [are] sufficiently specific to enable a person skilled in the art to practice the invention." *Pfaff*, 119 S.Ct. at 312, 48 USPQ2d at 1647.

[1] Denso claims that Tec Air offered the invention for sale on June 26, 1974 to Keeprite and on August 14, 1974 to Howard Industries, both prior to the critical date of September 24, 1974. According to Tec Air, although it ultimately shipped fans made according to the invention to these customers, it did not specify the balancing technique in its offers and it did not intend to use the patented one when it made the offers. Viewing the evidence in the light most favorable to Tec Air, we hold that the jury reasonably could have found that Tec Air's offers to Keeprite and Howard Industries did not raise the on-sale bar because the subject matter of these offers does not fully anticipate the claimed invention and Denso does not argue that it would have rendered the invention obvious.

Denso argues that no reasonable jury could have found that the reference to "balance plugs" on the August 16, 1974 drawing for the Keeprite fan meant anything other than balance plugs made according to the Swin patents because the mold was ultimately made with adjustable screws. The drawing itself sheds no light on the method of making the fan. To buttress its claim, therefore, Denso cites Dearhammer's testimony that he thought the notation referred to adjustable screws and that Tec Air employees called the adjustable screws "balance plugs." Tec Air's employee Richard Swin, Jr. testified, however, that the plastic lugs formed on the fan blade are called "balance plugs," regardless of the method used to create them. He also testified that Tec Air intended to use the brass plug method to balance the Keeprite fan when it made the August 1974 drawing and did not tell Dearhammer that adjustable screws would be used until October 29, 1974, when it sent him specifications for the first time. Dearhammer admitted that the sketch he used to quote a price for the Keeprite mold did not show adjustable screws. In light of this evidence, the jury reasonably could have found that Tec Air did not offer the patented invention for sale to Keeprite before the critical date.

Denso stresses that the August 1974 drawing shows that the invention was ready for patenting, thus satisfying the second prong of *Pfaff*. *See* 119 S.Ct. at 312, 48 USPQ2d at 1647. However, because the offer for sale did not involve subject matter that either anticipates the invention or would have rendered it obvious, *Pfaff*'s second prong is irrelevant. *Pfaff* did not remove the requirement that the subject matter of the commercial offer for sale "be something within the scope of the claim." *Scaltech*, 178 F.3d at 1383, 51 USPQ2d at 1058. Accordingly, Denso's reliance on *Pfaff* does not have the talismanic effect it desires.

Denso also argues that no reasonable jury could have found that the samples sent to Howard Industries with the August 14, 1974 offer letter were not made pursuant to the Swin patents because Tec Air received the modified mold the day before. It also claims that the sent fans must have had balance lugs made according to the patents because Howard Industries sent a letter in January 1975 asking Tec Air to move the "balancing lugs" on the 4B-60-21 fan. Tec Air argues that the jury reasonably could have found that the samples were made before August 13, 1974 because it had thousands of 4B-60-21 fans in inventory before it sent the mold to Mid City. Swin, Jr. testified that he selected the 4B-60-21 fan mold insert to be modified in part because Tec Air had a sufficient inventory of 4B-60-21 fans that it could ship while he tested the modified mold. Because balance lugs can be formed by several methods, the January 1975 letter does not indisputably show that Tec Air made the sent fans with the modified mold. Swin, Jr. testified, furthermore, that he did not make any fans from the modified mold until September 1974. Denso's argument relies on an inference that Tec Air immediately ran samples from the modified mold, despite Swin, Jr.'s testimony to the contrary. Although Swin, Jr. was an interested witness, the jury could have reasonably believed him in light of the large number of 4B-60-21 fans available in Tec Air's inventory. Therefore, the court did not err in denying Denso's motion for judgment as a matter of law on the issue of validity under section 102(b).

Obviousness

"Obviousness under 35 U.S.C. § 103 [(1994)] is a legal conclusion based on factual evidence," which we review "for correctness or error as a matter of law." *In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988) (internal quotations omitted). These factual underpinnings include

what a prior art reference teaches, whether a reference provides a motivation to combine its teachings with others, *see In re Beattie*, 974 F.2d 1309, 1311, 24 USPQ2d 1040, 1041-42 (Fed. Cir. 1992); whether the invention experienced commercial success, and whether it satisfied a long-felt, but unmet need, *see C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1351, 48 USPQ2d 1225, 1231 (Fed. Cir. 1998).

In reviewing "a jury special verdict on patent claim obviousness where the underlying facts have been disputed[,] . . . [w]e first presume that the jury resolved the underlying factual disputes in favor of the verdict winner and leave those presumed findings undisturbed if they are supported by substantial evidence. Then we examine the legal conclusion *de novo* to see whether it is correct in light of the presumed jury fact findings." *Jurgens v. McKasy*, 927 F.2d 1552, 1557, 18 USPQ2d 1031, 1035 (Fed. Cir. 1991) (citations omitted). The same rule also applies to special interrogatories.

To establish a *prima facie* case of obviousness, Denso must show "some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *Fine*, 837 F.2d at 1074, 5 USPQ2d at 1598. There is no suggestion to combine, however, if a reference teaches away from its combination with another source. *See id.* at 1075, 5 USPQ2d at 1599. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994). If when combined, the references "would produce a seemingly inoperative device," then they teach away from their combination. *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (CCPA 1969); *see also In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (finding no suggestion to modify a prior art device where the modification would render the device inoperable for its intended purpose).

Denso argues that the court should have granted its motion for judgment as a matter of law because the invention of the claims would have been obvious over U.S. Patent No. 3,136,001 ("the Gelbard patent") in combination with the brass plug method. Although Tec Air disclosed the Gelbard patent to the Patent and Trademark Office during prosecution of the Swin patents, the details of the brass plug method were not before the examiner. The Gelbard patent teaches using adjustable screws to create balance lugs on the blade tips of a molded fan. Unlike the screws of the Swin patents, these screws are accessible from the rear of the mold.

[2] Because, in the brass plug method, the operator drills the brass plugs from the cavity-side of the mold, combining this method with the teachings of the Gelbard patent results in cavity-side accessible screws. The Gelbard patent teaches, however, that each of its adjustable threaded members has "a non-threaded or smooth tip extending into a recess," which comes into contact with the molten plastic. Col. 1, ll. 64-67. This teaching is consistent with the conventional wisdom as late as 1974, which counseled against arranging screw heads to face the cavity-side of the mold because molten plastic would (1) enter the screw slot, which would be difficult to remove, and (2) likely seep behind the screw head and jam the screw, according to Tec Air's expert, Dr. Williamson. Because the brass plugs-Gelbard patent combination would be inoperable for its intended purpose—no screw driver would be able to turn the smooth-headed screws from the cavity-side of the mold—the jury reasonably could have found that the Gelbard patent taught away from its combination with the brass plug method.

Alternatively, even assuming that Denso established a *prima facie* case of obviousness, Tec Air presented sufficient objective evidence of nonobviousness to rebut it. "[O]bjective evidence of non-obviousness may be used to rebut a *prima facie* case of obviousness based on prior art references." *WMS Gaming Inc. v. International Game Tech.*, — F.3d —, —, 51 USPQ2d 1385, 1400 (Fed. Cir. 1999). This type of evidence "may include commercial success [and] long-felt but unsolved need." *Id.* "Whether the evidence presented suffices to rebut the *prima facie* case is part of the ultimate conclusion of obviousness and is therefore a question of law." *In re Rouffet*, 149 F.3d 1350, 1355, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998).

[3] According to the trial court, Tec Air presented evidence that millions of fans were sold by both Tec Air and Denso and that the patented method eliminated the "tedious, haphazard, and expensive process of drilling the surface of the mold cavity." Based on Tec Air's sales evidence, the jury reasonably could have found that the invention enjoyed commercial success. Denso argues that this evidence is insufficient because Tec Air failed to provide market share data. Although sales figures coupled with market data provide stronger evidence of commercial success, sales figures alone are also evidence of commercial success. *See Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1027, 226 USPQ 881, 888 (Fed. Cir. 1985) ("[I]nformation [about market share] might bolster the existence in fact of any commercial success . . . demonstrated by [mere sales data]. . . ."), *overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1358-61, 50 USPQ2d 1672, 1674-76 (Fed. Cir. 1999) (en banc); *see also In re Huang*, 100 F.3d 135, 140, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996) ("This court has noted in the past that evidence related solely to the number of units sold provides a very weak showing of commercial success, if any."); *see, e.g., Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ2d 1378, 1384 (Fed. Cir. 1997) ("[T]he record contains significant evidence of the commercial success of [the] invention. The record shows that [a competitor] sold over 14,800 dialysis machines allegedly incorporating the [claimed] invention since 1987."); *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1566, 1572, 41 USPQ2d 1641, 1643, 1648 (Fed. Cir. 1997) (affirming a finding that "sales evidence . . . shows [strong commercial] success," where the "sales evidence" consisted solely of the patentee's "$17 million of sales from 1979 through 1984, and its $4 million of annual sales from 1985 through 1989").

Denso also argues that Tec Air failed to show a nexus between the sales and the patented invention. "A *prima facie* case of nexus is generally made out when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent." *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392, 7 USPQ2d 1222, 1226 (Fed. Cir. 1988). The evidence shows that Tec Air sold approximately two million fans per month, all of which were made according to the patented method. *See Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1481, 1 USPQ2d 1241, 1246 (Fed. Cir. 1986) (finding commercial success where a product made by a patented method was commercially successful).

According to the trial court, Tec Air also offered testimony that "there was a long-felt but unmet need to create a more efficient method to achieve fan balance" prior to the Swin patents. Swin, Sr. testified that Tec Air used several unsatisfactory balancing techniques before adopting the patented one. Dr. Williamson testified that the industry experienced problems with the prior art machining methods. Moreover, after Denso ceased infringing the Swin patents, it had to resort to less effective methods of balancing the fans. Based on this evidence, the jury reasonably could have found there was a long-felt but unmet need in the prior art for an improved balancing method, which the Swin patents satisfied.

In light of this objective evidence of nonobviousness and the lack of evidence of a suggestion to combine the references, the court properly denied Denso's motion for judgment as a matter of law on the obviousness issue.

Damages

In addition to arguing that the court should have granted its motion for judgment as a matter of law on the damages issue, Denso argues that the court should have granted a new trial on this issue. We review the trial court's denial of a motion for a new trial for abuse of discretion. *See DMI, Inc. v. Deere & Co.*, 802 F.2d 421, 427, 231 USPQ 276, 280 (Fed. Cir. 1986). "That question turns on whether an error occurred in the conduct of the trial that was so grievous as to have rendered the trial unfair." *Id.*

The jury awarded damages based on the entire market value rule, "which permits recovery of damages based on the value of the entire apparatus containing several features, where the patent related feature is the basis for customer demand." *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1580, 12 USPQ2d 1026, 1031 (Fed. Cir. 1989). The entire market value rule is appropriate where both the patented and unpatented components together are "analogous to components of a single assembly," "parts of a complete machine," or "constitute a functional unit," but not where the unpatented components "have essentially no functional relationship to the patented invention and . . . may have been sold with an infringing device only as a matter of convenience or business advantage." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1550, 35 USPQ2d 1065, 1073 (Fed. Cir. 1995) (en banc).

[4] Denso argues that the jury could not have reasonably found that (1) the patented and unpatented components comprised a single functional unit and (2) the basis for the customer demand was the method of balancing the fan inside the assembly. Denso's

damage expert testified that the motors used with the radiator and condenser assemblies required fans. Denso did not sell these assemblies without fans. Denso's internal documents stress, moreover, that the performance and price of the *entire system* were paramount to its customers. This evidence amply supports the finding that the assemblies were a single functional unit. In addition, the evidence shows that customers wanted fans that were balanced to a certain specification and once Denso abandoned the patented method, it could not meet the 2.0 gm-cm balance specification. Denso argues that its customers did not care how the fans in the assemblies were balanced. However, after Denso changed its specification, one customer complained and required Denso to rebalance the fans. From this evidence, the jury could have reasonably concluded that the demand for the entire assembly depended on the patented invention.

Thus, the jury properly applied the entire market value rule and Denso failed to demonstrate that the trial court legally erred in denying its motion for judgment as a matter of law or abused its discretion in declining to grant a new trial on the damages issue.

Conclusion

Accordingly, the judgment of United States District Court for the Northern District of Illinois is affirmed.

AFFIRMED

U.S. Patent and Trademark Office
Trademark Trial and Appeal Board

CTRL Systems Inc. v. Ultraphonics of North America Inc.

Opposition No. 96,623

Decided August 17, 1999

Released September 30, 1999

TRADEMARKS AND UNFAIR TRADE PRACTICES

1. Practice and procedure in Patent and Trademark Office — Interpartes proceedings — Opposition and cancellation — In general (§325.0305.01)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Dismissal; default judgment (§410.32)

Trademark Trial and Appeal Board has discretion to reopen case under Fed. R. Civ. P. 60(b) when judgment was entered due to dismissal for failure to prosecute, since law favors determination of cases on merits.

TRADEMARKS AND UNFAIR TRADE PRACTICES

2. Practice and procedure in Patent and Trademark Office — Interpartes proceedings — Opposition and cancellation — In general (§325.0305.01)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Dismissal; default judgment (§410.32)

Under present law, party is held accountable for acts or omissions of its counsel, and distinction between neglect of counsel and neglect of party is thus irrelevant; client and attorney share duty to remain diligent in prosecuting or defending case, and action, inaction, or even neglect by client's attorney will not excuse inattention of client so as to yield client another day in court.

TRADEMARKS AND UNFAIR TRADE PRACTICES

3. Practice and procedure in Patent and Trademark Office — Interpartes proceedings — Opposition and cancellation — In general (§325.0305.01)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Dismissal; default judgment (§410.32)

Opposer's motion to set aside judgment for applicant and reopen cancellation proceeding is denied, since opposer is equally as accountable as its counsel for lack of attention to case, and since opposer did not communicate with its attorney regarding responses to discovery requests, which were never served, and although opposer's counsel should have notified it of Trademark Trial and Appeal Board's order to show cause why judgment should not be entered for applicant, opposer was not in regular contact with counsel, did not obtain new counsel for two years after its attorney ended association with firm, and did not file motion to reopen for at least four months after learning of dismissal of case for failure to prosecute.

Opposition of CTRL Systems Inc. to application of Ultraphonics of North America Inc. for registration of trademark. Following

judgment for applicant, opposer moves to reopen opposition and cancel registration. Denied.

Before Seeherman, Quinn and Rogers, administrative trademark judges.

Rogers, J.

Judgment was entered against opposer and the opposition was dismissed, pursuant to Trademark Rule 2.128(a)(3), after opposer failed to file a brief on the case and failed to respond to an order to show cause why such judgment should not be entered. Since we entered judgment, the Office issued applicant a registration. Opposer has both moved to reopen this opposition under Fed.R.Civ.P. 60(b) and petitioned to cancel the registration. The motion to reopen is supported by a declaration and exhibits from opposer's president, Robert Roche.

In response to opposer's motion to reopen, applicant filed "Registrant's [sic] Brief in Response to Motion to Dismiss [sic]." The filing is, in fact, a response to the motion to reopen. Opposer then filed a reply brief supported by a supplemental declaration from Mr. Roche and applicant then filed a "rejoinder." In addition, applicant filed notice of the filing of the petition for cancellation and urges that, as a result, the Board has no need to consider the motion to reopen.[2] Opposer argues that the motion to reopen should be decided. We agree. Our decision on the motion to reopen will determine whether the judgment already entered will stand or fall. If the judgment is allowed to stand, it may have claim preclusive effect for the cancellation proceeding.[3]

[1] The law favors determination of cases on the merits; and when circumstances dictate that a judgment by way of default or dismissal for failure to prosecute should be set aside, the Board will exercise its discretion under Fed.R.Civ.P. 60(b) to reopen the case. We begin by reviewing the history of this case.

CHRONOLOGY OF CASE

The notice of opposition was filed in early April 1995 and the answer was timely filed in late May 1995. On June 27, 1995, the Board issued a discovery and trial schedule.

On July 17, 1995, opposer moved, with the consent of applicant, to reset discovery and trial dates. The motion included an agreement to reset the time for opposer to respond to applicant's discovery requests until September 20, 1995.

On July 19, 1995, applicant corresponded with opposer about the case; however, neither a copy of the letter nor a summary of its contents has been provides. Several telephone conversations about the case followed, though the content of the conversations has not been revealed. On August 2, 1995, opposer wrote to applicant about the case. Opposer's letter suggested settlement as an alternative to litigation, though no specific terms were proposed.

On September 5, 1995, opposer filed a second consented motion to extend discovery and reset trial dates. As a result, opposer's trial period was set to run from February 23, 1996 to March 24, 1996. In "late 1995," Mr. Roche reports, opposer was experiencing financial trouble and he requested counsel to "delay the opposition proceeding." There is no report of counsel's response.[4]

In January 1996, opposer's attorney left the firm with which he was associated. "Throughout 1996 and 1997," Mr. Roche reports, he "was in contact initially with the accounting office, and later with partners, of [opposer's] law firm to work out payment of fees."

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[1] Applicant argues that it is now a registrant, not an applicant, and that there is no authority which would allow the Board to "withdraw" the registration. Applicant is mistaken. The Board has the discretion to grant opposer's motion under Rule 60(b) and, if the motion were granted, the Assistant Commissioner for Trademarks would, as a ministerial act, cancel the registration that issued to applicant and reinstate the underlying application. *See* TBMP §545, and *National Telefilm Associates, Inc. v. Craig Denney Productions*, 228 USPQ 61 (Comm'r Pat. 1985). For the purposes of the referenced cancellation petition, Ultraphonics of North America, Inc. may call itself a registrant. For the purposes of this opposition, its designation remains "applicant."

[2] The Trademark Rules of Practice were amended in October 1998 to, among other things, bar the filing of any papers beyond a reply brief on a motion. In this case, the additional papers have been considered because the parties briefed the issues prior to the change in the rules.

[3] See Marc A. Bergsman, TIPS FROM THE TTAB: The Effect of Board Decisions in Civil Actions; Claim Preclusion and Issue Preclusion in Board Proceedings, 80 TradeMark Rep. 540 (1990).

[4] We have given little weight to applicant's lengthy arguments regarding Mr. Roche's admission that he wished to delay prosecution of this case. There is no evidence that counsel for opposer agreed to pursue a course of delay and the facts of the case clearly suggest otherwise. Nor is there any merit in applicant's argument that the two stipulated extensions of discovery evidence delay. They were agreed to by the parties during a period when it appears there were at least some preliminary discussions regarding settlement.

APPENDIX 'F'

Shmuel, for trademark infringement. On defendant's motion for partial summary judgment. Motion denied.

Thomas Schultz, and Holland & Knight, both of Miami, Fla., and Thomas F. Reddy, Jr., John J. Lauter, Jr., Brian D. Coggio, Terese R. Cohen, and Pennie & Edmonds, all of New York, N.Y., for plaintiff.

Harley Tropin, and Kozyak, Tropin & Throckmorton, both of Miami, Fla., for defendant.

Davis, District Judge.

THIS MATTER is before the Court on Defendant's Motion for Partial Summary Judgment. This case involves a Complaint for infringement of the trademark "Big Ben," seeking injunctive relief and damages under a variety of legal theories, including the Lanham Act and principles of federal and Florida unfair competition. The Sixth Claim for Relief alleges a violation of the Florida Deceptive and Unfair Trade Practices Act, *Fla. Stat.* Section 501.201, *et seq.* Defendants insist that the Florida Statute is only applicable to consumer transactions or to sales in which the Plaintiff has not previously been engaged in the business involved. Section 501.211(1), however, grants an additional right to a private action:

> without regard to any other remedy or relief to which a person is entitled, *anyone aggrieved* by a violation of this part may bring an action to obtain a *declaratory judgment* that an act or practice violates this part and to *enjoin* a supplier who has violated . . . this part.

(emphasis added). Absent any modifying language, this Section of the statute includes a broader category of complainants than merely consumers.[1] In contrast, Section 501.211(2) grants actual damages as well as attorney's fees to any *consumer* who has suffered a loss as a result of a violation of the statute. The choice of the word "anyone" instead of the word "consumer" in 501.211(1), therefore, seems deliberate, and implies that the scope of the enjoinder remedy is greater than that of the actual damage remedy.[2]

The Court in *L.J.S. Co. v. Marks,* 480 F.Supp. 241 (S.D. Fla. 1979), while denying a non-consumer damages under the Act, implied that a declaratory judgment and an injunction would have been available. Furthermore, in *United Feature Syndicate, Inc. v. Sunrise Mold Co.,* 569 F.Supp. 1475 (S.D. Fla. 1983) (J. Paine), the Court construed the Act to protect owners of copyrights from infringement.

[1] Although the statute is generally directed at traditional consumer transactions and its purpose is to protect the unsophisticated from being conned into unsound investments, *See Black v. Department of Legal Affairs,* 468 So. 2d 451 (1985), the extension of the statute's scope to others damaged by unfair trade practices is not unique. Many jurisdictions have interpreted similar consumer protection statutes to encompass trademark violations that could cause confusion and misunderstanding to the average consumer.[3] Therefore, it is:

ORDERED AND ADJUDGED that Defendants' motion is hereby DENIED.

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[1] Defendants do not here contest that Plaintiff is not "aggrieved" within the meaning of the section.

[2] In *IC Industries v. I.C. Indus.,* 595 F.Supp. 340 (M.D. Fla. 1983) the court construed Section 501.212(3) to exclude trademark cases from the Act. That Section excludes "a claim for damage to property other than the property that is the subject of the consumer transaction." Nothing in that Section, however, excludes Plaintiff from seeking a *declaratory judgment* and an *injunction* to prevent continued infringement of its trademark.

[3] *See* 89 ALR 3d 449, 468 for cases where courts held that the use of tradenames constituted a violation of a deceptive trade practice statute or consumer protection act.

Court of Appeals, Federal Circuit

Akzo N.V. v. U.S. International Trade Commission

No. 86-877.

Decided December 22, 1986

PATENTS

1. Patentability/Validity — Anticipation — Prior art (§115.0703)

U.S. International Trade Commission did not use impermissible "ipsissimus verbis" test in finding that claimed process for making aramid fibers was not anticipated, but rather properly found that prior art did not disclose such process to one of ordinary skill in art and that prior art reference that called for use of sulfuric acid did not call for use of 98 percent concentration critical to success of claimed process, since "concentrated sulfuric acid" is not inherently 98 percent sulfuric acid to one skilled in art.

2. U.S. International Trade Commission — In general (§115.01)

International Trade Commission's administrative protective order which permitted access, to confidential business information produced during discovery phase of investigation, by both parties' outside counsel, but not by management personnel or in-house counsel of either company was proper, since order did unilaterally immunize purportedly confidential documents from scrutiny of party challenging order, since order provided mechanism by which either party was free to object to designation of information as confidential, and since party challenging order failed to prove need for access to such information, nor harm to it from nondisclosure.

3. U.S. International Trade Commission — Burden of proof (§115.05)

International Trade Commission did not err in determining that unlawful importation of infringing aramid fibers violated Tariff Act's Section 337, 19 USC 1337, based upon its finding, supported by substantial evidence, that such importation will have tendency to injure domestic industry, despite evidence that domestic industry's profits from sale of fibers will increase notwithstanding such entry into market, since issue under Section 337 is not whether domestic industry profits will increase beyond current levels but whether importer's presence in market will substantially injure domestic industry's business during remaining life of patent.

4. U.S. International Trade Commission — Jurisdiction (§115.03)

International Trade Commission proceeding under Tariff Act's Section 337, 19 USC 1337, is not "inherently judicial" proceeding that must be adjudicated only by Constitution's Article III courts, even though private rights may be affected by Section 337 proceedings, since main thrust of Section 337 is to protect public interest from unfair trade practices in international commerce, and since Section 337 represents valid delegation of broad congressional power to achieve such purpose.

Appeal from U.S. International Trade Commission.

U.S. International Trade Commission investigation on behalf of E.I. du Pont de Nemours and Co., for exclusion of certain aramid fibers covered by U.S. patent, in which Akzo N.V., Enka B.V., Aramide Maatschappij v.o.f., and Akzona Incorporated, were designated as respondents. From exclusion order prohibiting importation, respondents appeal. Affirmed.

Denis McInerney, and Cahill Gordon & Reindel, both of New York, N.Y., C. Frederick Leydig, and Leydig, Voit & Mayer Ltd., both of Chicago, Ill., and Tom M. Schaumberg, Cecilia H. Gonzalez, and Plaia & Schaumberg, Chartered, all of Washington, D.C. (David R. Hyde, Laurence T. Sorkin, George Wailand, P. Kevin Castel, Charles S. Oslakovic, John Kilyk, Jr., Norval B. Galloway, and Robert H. Falk, and Hubbard, Thurman, Turner & Tucker, both of Dallas, Texas, on the brief), for appellants.

Catherine Field, Office of the General Counsel, U.S. International Trade Commission (Michael P. Mabile, assistant general counsel, on the brief), for appellee.

Daniel M. Gribbon, and Covington & Burling, both of Washington, D.C., Joseph M. Fitzpatrick, and Fitzpatrick, Cella, Harper & Scinto, both of New York, N.Y. (Harris Weinstein, James R. Atwood, Eugene D. Gulland, Dwight C. Smith, III, and Stephen H. Marcus, and John A. O'Brien, Henry J. Renk, Charles P. Baker, Laura A. Bauer, and Bruce C. Haas, on the brief), for intervenor-appellee E.I. du Pont de Nemours.

Before Markey, Chief Judge, and Davis and Nies, Circuit Judges.

Davis, Circuit Judge.

This is an appeal by Akzo, N.V., Enka B.V., Aramide Maatschappij v.o.f. and Akzona Inc. (appellants or Akzo) from an exclusion order by the United States International Trade Commission (Commission or trial tribunal) pursuant to §§337 and 337a of the Tariff Act of 1930, 19 U.S.C. §§1337, 1337a (1982), prohibiting the importation into the United States of aramid fibers manufactured by Akzo in the Netherlands. We affirm.

I. *Background; Issues; Scope of Review*

A. Background. On April 18, 1984, E.I. du Pont de Nemours and Company (appellee or Du Pont) filed a complaint with the Commission under §337 of the Tariff Act of 1930 (19 U.S.C. §1337).[1] The complaint alleged that Akzo had engaged in unfair methods of competition and unfair acts including the importation, sale and marketing in the United States of certain aramid fibers.[2] produced in the Netherlands by a process purportedly covered by the claims of Du Pont's U.S. Letters Patent No. 3,767,756 (the Blades or '756 patent). In addition, the complaint charged Akzo with attempting both to exploit applications of aramid fibers and to penetrate markets for aramid fibers created by Du Pont. Finally, the complaint alleged that the effect or tendency of the unfair methods of competition and unfair acts was to destroy or substantially injure an industry, efficiently and economically operated, in the United States.

After evaluating Du Pont's complaint, the Commission instituted an investigation pursuant to §337(b), 19 U.S.C. §1337(b), and an administrative law judge (ALJ) was assigned to preside over the investigation.

The major substantive question before the ALJ (and now before us) is the validity and enforceability of Du Pont's Blades patent. Those issues, and the related facts and circumstances, are set forth and discussed in Part II, *infra*. The major procedural issue is whether Akzo was denied due process because Du Pont's confidential documents were not disclosed to appellants' management. This problem (together with an alleged violation of treaty rights) is considered in Part III, *infra*. The other issues presented to us are dealt with in Part IV, *infra*.

Following 14 days of hearing the ALJ issued an initial determination holding that there was a violation of §337(a) of the Tariff Act of 1930 in the unlawful importation or sale of certain aramid fibers produced overseas by means of a process that if practiced in the United States would infringe the Blades '756 patent, and that importation has the tendency to injure substantially an efficiently and economically operated industry in the United States.

Akzo filed a petition for review of the ALJ's initial determination on June 3, 1985. On July 15, 1985, the Commission decided to review only those portions of the initial determination pertaining to anticipation and obviousness of the Blades '756 patent under 335 U.S.C. §§102 and 103. Ultimately, the Commission affirmed the ALJ's findings and conclusions on anticipation and obviousness and determined that appellants had failed to prove the Blades '756 patent invalid. Having decided not to review the remainder of the initial determination, the Commission concluded that there was a violation of §337. Accordingly, on November 25, 1985, the Commission, after further consideration, entered an exclusion order limited to certain forms of aramid fibers produced by Akzo. The Commission's order became final on January 25, 1986 when the President declined to overrule it pursuant to §337(g).

B. *Issues.* On this appeal, Akzo raises a number of issues for us to resolve:

(1) whether the Commission's finding that claim 13 of the '756 patent was "not invalid" and "not unenforceable" is supported by substantial evidence;[3]

(2) whether Akzo's due process and treaty rights were violated in the Commission proceeding;

(3) whether the Commission, as a non-Article III tribunal, is constitutionally prohibited from adjudicating the validity and enforceability of patents;

(4) whether the Commission's finding that Akzo's sales of aramid fibers in the United States would have a tendency to "destroy or substantially injure" an industry economically and efficiently operated is supported by substantial evidence;

(5) whether the Commission's conclusion that Du Pont's value-in-use pricing did not violate the antitrust laws is correct and supported by substantial evidence; and

(6) whether it is a defense to Du Pont's complaint that Du Pont employed a solvent included in a polymerization process patented by Akzo.

C. *Scope of review.* This court defined our scope of review in cases appealed from the Commission in *Beloit Corp. v. Valmet OY*, (Order), 742 F.2d 1421, 223 USPQ 193 (1984), *cert. denied*, 105 S. Ct. 2706, 86 L. Ed. 2d 721 (1985). There we held that the court "does not sit to review what the Commission has not decided." 742 F.2d at 1423, 223 USPQ at 194. *Beloit* is distinguishable from this case because there the Commission specifically adopted only a portion of the presiding official's initial decision. *See, e.g., American Hospital Supply Corp. v. Travenol Laboratories, Inc.*, 745 F.2d 1, 5 n.13, 223 USPQ 577, 580 n.13 (Fed. Cir. 1984). In contrast, in the current case, the Commission merely determined not to review the remainder of the initial decision, choosing to conduct its own §§102 and 103 analysis. The Commission neither rejected any part of the initial determination nor did it say that it was taking no position on any part of it. Although the Commission limited its own review to patent validity under §§102 and 103, the fact that it affirmed the conclusion of the ALJ that there as a §337 violation makes reviewable those conclusions of the ALJ necessary for the Commission to have determined (as it did) that there was a §337 violation. *Accord Warner Brothers, Inc. v. U.S. International Trade Commission*, 787 F.2d 562, 229 USPQ 126 (Fed. Cir. 1986). This includes not only the §§102 and 103 issues of anticipation and obviousness, but also whether there was inequitable conduct before the Patent Office and the other issues decided by the Commission and the ALJ.[4]

II. Validity and Enforceability of the Blades Patent

A. *The Invention.*[5] The Blades '756 patent, "Dry-Jet Wet Spinning Process," was issued on October 23, 1973 to Dr. Herbert Blades and immediately assigned to Du Pont. The patent describes a method that produces a high strength synthetic polyamide[6] fiber which Du Pont has marketed under the trade name Kevlar. This fiber has an extraordinary as-spun strength, five times stronger pound for pound than steel, as well as a modulus (stretch resistance) equal to glass, eight times as high as industrial grade polyester, and twenty-five times as high as industrial nylon. Kevlar is also much more heat resistant than industrial-grade nylon or polyester. These extraordinary physical properties, as well as Kevlar's light weight and rustproof character, have enabled Du Pont to market it for use in a variety of applications including, but not limited to, roping, spacecraft and airplane parts, bullet resistant clothing and armor, tires, and boat hulls. Depending upon its use, Kevlar has been used as a substitute for steel, aluminum, asbestos, nylon, rayon, polyester, cotton, or cotton fiber. Kevlar is available as either a continuous rope or filament, or alternatively as a staple or pulp. Staple consists of short filaments which can be spun into yarn. Pulp is ground fiber most often used as an asbestos substitute.

The procedure by which the synthetic fiber is manufactured involves dry spinning polyamides from coagulation solutions called dopes. In dry spinning, a specialized filter called a spinneret is placed a short distance from a bath of spinning dope that is extruded through a layer of gas and into an aqueous

[1] 19 U.S.C. §1337 (1976) provides in pertinent part:

> Unfair practices in import trade
>
> (a) Unfair methods of competition declared unlawful
>
> Unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States, are declared unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provisions of law, as provided in this section.

[2] As indicated in Part II, *infra*, aramid fibers are the strongest commercial synthetic fibers known to man — about five times stronger than steel on an equal weight basis.

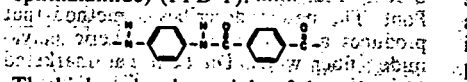
[3] Akzo presents no contention that, if claim 13 of the '756 patent is valid and enforceable, Akzo would not infringe if it used its same process in this country.

[4] 19 C.F.R. §210.53(h)(1986) provides that "[a]n initial determination . . . shall become the determination of the Commission . . . unless the Commission . . . shall have ordered review of the initial determination or certain issues therein . . . ." In accepting the necessary conclusions of the ALJ we do not hold that the Commission must have concurred with each and every individual factual finding of the ALJ to support its conclusion.

[5] Our recitation of the facts follows the ALJ's and the Commission's findings which are supported by at least substantial evidence. *See Surface Technology, Inc. v. U.S. International Trade Commission*, 801 F.2d 1336, 1340, 231 USPQ 192, 195 (Fed. Cir. 1986).

[6] Polyamides are polymers containing amide linkages. Aromatic polymers are polyamides where the radicals linking the amide linkages constitute aromatic radicals. The polymer described in claim 13 of the Blades '756 patent is a wholly aromatic para-positioned polyamide.

coagulation bath.[7] The dope used in the Blades '756 patent consists of para-positioned aromatic polyamides dissolved in highly concentrated sulfuric acid and heated to around 100°C. The polyamide used is a high molecular weight poly(p-phenylene terephthalamide) (PPD-T).



The high molecular weight of the polyamide results in a high inherent viscosity[8] of approximately 4.4% when 20% PPD-T by weight is dissolved in approximately 100% sulfuric acid.

In 1969 Dr. Blades, one of Du Pont's research scientists, began to develop and conduct experiments aimed at producing a high-strength synthetic fiber. Blades exclusively employed a wet-spinning method in his early work, using PPD-T as well as other polymers. This early work had minimal success. Although the dry-spinning method was known by Du Pont scientists, a 1966 report indicated that the low solubility of PPD-T precluded use of the dry-spinning technique. In 1969, Du Pont's Dr. Peter Boettcher suggested to Blades that dry spinning might improve the end-results by influencing coagulation. Dr. Boettcher had learned about dry spinning from a Monsanto Morgan patent (Morgan '645 patent).

Blades' early experimentation with the dry-spinning process did not yield fiber with an increased tenacity despite the fact that dry spinning was known to improve fiber tenacity using other dopes. Blades' initial conclusion was that dry spinning would be unsuccessful with PPD-T. Nevertheless, he continued experimenting with the dry-spinning process, and, at his supervisor's suggestion, began using sulfuric acid as a solvent. Blades also redesigned and built a mixing device because of some difficulties he encountered mixing PPD-T with the sulfuric acid. Sulfuric acid was not an evident candidate as a solvent because it was known to react with the polymer and become degraded at high temperatures. Blades discovered, however, that he could produce an improved fiber using 10.2% polyamide in about 100% sulfuric acid. Under this system he found that there was no difference in tensile strength of the fiber using a wet-spun or dry-spun method. PPD-T was a somewhat unusual choice of polymer for this work because of its characteristic rigidity caused by the placement of para-oriented aromatic rings in the chain. The para-positioning of the aromatic rings makes the polyamide much less soluble than analogous meta-positioned rings. But the fact is that, while meta-positioned polymers generally form only isotropic solutions, para-positioned polymers of Blades' invention form anisotropic solutions[9] at high concentrations.

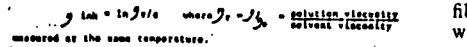
In subsequent trials, Blades increased the concentration of PPD-T and obtained a significantly improved fiber, especially using the dry-spinning method. When the system was operated at room temperature, however, he found that undissolved polyamide clogged up the holes of the spinneret. He therefore heated the dope at these higher concentrations to dissolve all the polyamide and keep the system above the melting point. To his surprise, Blades discovered that there was little or no degradation of the polyamide at high temperatures. He explained this unexpected absence of degradation by theorizing that, when the system contains high concentrations of PPD-T, the sulfuric acid binds to the polymer and chemically deactivates it.

After numerous trials, Blades found that an optional fiber could be produced using PPD-T of 4.4 inherent viscosity at a 20% concentration in approximately 100% sulfuric acid. The dope was then heated to 95°C and dry spinning was then carried out at about 100°C. The resultant fiber had a tenacity of approximately two times that of previous experimental fibers.

In April 1971, Blades filed an application with the PTO claiming the method of making these aramid fibers. the initial application and two subsequent applications were rejected in large part on the basis of anticipation by the Morgan '645 and the Kwolek '542 patents which Du Pont had brought to the attention of the examiner. Initially the

[7] Dry spinning can be contrasted with wet spinning where the spinneret is placed directly into the spinning dope. Wet spinning is the process used to make a number of synthetic fibers including rayon and nylon.

[8] Inherent viscosity (inh) is a measure of viscosity used in polymer chemistry.



measured at the same temperature.

[9] An anisotropic solution exhibits optical birefringence (i.e., the liquid crystalline solution refracts light in two directions). This characteristic imparts a high degree of orientation to the spun fibers yielding a stiffer and stronger end product without requiring post-coagulation drawing as is required is other man-made fibers such as nylon and rayon.

examiner also rejected the application under 35 U.S.C. §103. Blades, however, was able to overcome the examiner's objections, and on May 2, 1973, the PTO gave notice of allowance of the Blades '756 patent. Blades assigned the patent rights to Du Pont.

B. *Validity.* Claim 13, the narrowest claim, is the only claim involved on this appeal.[10] Akzo says that that claim is invalid under 35 U.S.C. §§ 102 and 103. More specifically, Akzo argues that the Commission misconstrued the legal standard of anticipation and therefore erroneously held that the Blades '756 patent was not anticipated. In addition, appellants argue that the Commission failed properly to evaluate the prior art in determining obviousness *vel non*. Of course, it goes without elaboration that the Blades '756 patent enjoys a presumption of validity under 35 U.S.C. §282.

[1] As we have said, Akzo challenges the Commission's use of §102, claiming that that tribunal misinterpreted the legal standard of anticipation. Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). In addition, the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964). Akzo asserts, however, that the Commission wrongly used an *"ipsissimis verbis* test" in reaching its conclusion that the Blades '756 patent was not anticipated by the Morgan '645 disclosure.[11] We do not read the Commission's opinion as requiring such an *"ipsissimis verbis* test." Rather, we understand that opinion as simply finding that the prior art reference did not disclose, to one of ordinary skill in the art,[12] the process for making the aramid fibers described in claim 13. The Commission noted that while the Morgan '645 patent called for the use of sulfuric acid, it did not call for the use of at least 98% concentrated sulfuric acid which was critical for the success of the Blades process. The Commission also concurred with the ALJ and found that concentrated sulfuric acid is not inherently 98% sulfuric acid to one skilled in the art.

Because we determine that the Commission did not use an incorrect legal standard under §102, we are bound to accept its and the ALJ's factual findings if supported by substantial evidence. 5 U.S.C. §706 (1982). As appellants themselves point out, anticipation under §102 is a factual determination. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984). We must conclude that there is substantial evidence in the record supporting the Commission's conclusion that claim 13 of the Blades '756 patent was not anticipated by the prior art. As the Supreme Court noted in *Universal Camera v. NLRB*, 350 U.S. 474, 488 (1951), the substantial evidence standard does not allow a court to conduct a *de novo* investigation of the evidence on the record before it and reach an independent conclusion; rather, the court's review is limited to deciding whether there is sufficient evidence in the record considered as a whole to support the agency's findings. The mere fact that a reasonable person might reach some other conclusion is insufficient for this court to overturn the agency's conclusion. *See SSIH Equipment S.A. v. U.S. International Trade Commission*, 718 F.2d 365, 381, 218 USPQ 678, 691 (Fed. Cir. 1983) (additional views of Judge Nies).

The ALJ concluded, after extensive analysis, that the claimed invention of the Blades '756 patent was not anticipated by prior art, including the Morgan '645 patent. He noted that, while the Morgan '645 patent teaches the use of an airgap, the use of airgap in and of itself does not guarantee an improved fiber. This was obvious from Blades' early work. The ALJ also found that sulfuric acid in any concentration was not disclosed as a solvent in the Morgan '645 patent; or did that patent disclose PPD-T in its optically anisotropic state. Moreover, the ALJ found that the Morgan '645 patent was not an enabling disclosure with regard to the claimed spinning dope. Neither the 18% concentration of PPD-T nor the heating of the dope to achieve this concentration was disclosed in the Morgan '645 patent. The ALJ also rejected appellants' arguments that the

[10] Claim 13 reads as follows:

A method comprising extruding a spinning dope from an orifice through a layer of gas and into an aqueous bath at a temperature of under 50°C said dope comprising a polyamide and a solvent of sulfuric acid of at least 98% concentration at a concentration of at least 40 grams of said polyamide per 100 ml. of solvent, said polyamide having an inherent viscosity of at least 3.0 and being poly(p-phenylene terephthalamide).

[11] An *"ipsissimis verbis"* test requires the same terminology in the prior art in order to find anticipation.

[12] The Commission made specific findings on the skill of the art. It concluded that the skill in the art was high — that of a doctorate or post-doctorate in chemistry.

Blades process was anticipated by the Hill and Smith patents which were referenced in the Morgan '645 patent. This would have required Blades randomly to pick and choose among a number of different polyamides, a plurality of solvents, and a range of inherent viscosities. The ALJ rejected such "random picking and choosing" of prior art, relying on *In re Arkley*, 455 F.2d 586, 587, 172 USPQ 524, 526 (CCPA 1972), and concluded in effect that the anticipatory reference must disclose in the prior art a thing substantially identical with the claimed invention. In a somewhat more limited consideration — restricted to the concentration of sulfuric acid in the Blades patent — the Commission itself reached the same result.

Accordingly, we hold that there is substantial evidence in the record as a whole to sustain the Commission's (including the ALJ's) findings that the Blades process was not anticipated by any prior art.[13]

Appellants say, as an alternative to their §102 argument, that the trial tribunal erred when it failed to find that the Blades '756 patent would have been obvious under 35 U.S.C. §103 in view of the Morgan '645 and Kwolek '542 patents. It is now established that obviousness is a question of law based on factual inquiries which include:

(1) the scope and content of the prior art;
(2) the difference between prior art and the claims at stake;
(3) the level of ordinary skill in the art; and
(4) objective evidence of nonobviousness (secondary factors).

Such objective indications as commercial success and long-felt but unresolved needs, failure of others, copying, and unexpected results are relevant facts relating to the issue of validity. *See, e.g., In re DeBlauwe*, 736 F.2d 699, 222 USPQ 191 (Fed. Cir. 1984) (obviousness a question of law to be determined on the facts). Since obviousness is a question of law, we are not bound by the Commission's ultimate determination on the matter of §103 obviousness. *See Corning Glass Works v. U.S. International Trade Commission*, 799 F.2d 1559, 1565 & n.5, 230 USPQ 822, 826 & n.5 (Fed. Cir. 1986).

In the proceedings before the Commission, Du Pont premised its defense of nonobviousness on the basis that the prior art — mainly that the Morgan '645 patent and the Kwolek '542 patent — actually led away rather than toward the Blades process. The Commission found Du Pont's expert witness' testimony to be compelling. That witness, Dr. Uhlmann, explained why the Morgan '645 patent, when considered with other prior art references, including the Kwolek '542, Bair '941, and Cipriani '793 patents, would not have rendered the invention of Blades '756 patent obvious. The Kwolek '542 patent calls for conventional wet or dry spinning and calls for concentrations of PPD-T far lower than required by the Blades process. The Bair '941 patent does not disclose heating sulfuric acid with PPD-T to achieve an anisotropic solution. While the Morgan '745 patent discoses air-gap spinning, its emphasis is on meta-oriented polymers. Based on these differences, Dr. Uhlmann concluded that one skilled in the art would *not* combine them or be led to the Blades invention.

As the ALJ recognized, prior art references before the tribunal must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Moreover, appellants cannot pick and choose among individual parts of assorted prior art references "as a mosaic to recreate a facsimile of the claimed invention." 721 F.2d at 1552, 220 USPQ at 312. In this case, the ALJ found that Akzo's expert witnesses could not show how the prior art patents could be brought together to render the Blades '756 invention obvious without reconstructing the teachings of those patents assisted by hindsight.

The secondary considerations also compelled the Commission to make a finding of nonobviousness. The commercial success of Du Pont's Kevlar patent has been enormous and its range of uses substantial. Du Pont is still developing commercial applications for Kevlar, having spent significant amounts of money in developing both new uses and new markets for the product. Commercial success is, of course, a strong factor favoring non-obviousness. *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575–76, 222 USPQ 774, 777, (Fed. Cir. 1984), *cert. denied*, 471 U.S. 1065 (1985). Moreover, as the ALJ noted, Blades solved a problem that Du Pont research scientists had been tackling for years. The Blades process represents a solution to a long-felt need and practitioners in the field immediately recognized that that process was a remarkable advancement in polymer spinning technology. Indeed, as brought out in this appeal, even one of Akzo's scientific reports repeatedly expressed concern for degradation of PPD-T and amazement at the disclosure of the Blades '756 process.

We agree, therefore, with the Commission's determination that the Blades '756 patent is not invalid for anticipation or obviousness.

C. *Alleged inequitable conduct before the Patent and Trademark Office (PTO).* Appellants urge that Du Pont misled the patent examiner in two respects: first, that Du Pont submitted an affidavit to overcome the examiner's obviousness objections that failed to compare the Blades process with the closest prior art; and, second, that Du Pont persistently argued that the Morgan '645 patent and the Kwolek '542 patent did not anticipate the Blades patent.

In *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 223 USPQ 1089 (Fed. Cir. 1984), *cert. denied*, 106 S. Ct. 73 (1985), this court articulated a two-prong test for establishing inequitable conduct before the PTO. To render a patent unenforceable, the proponent of the inequitable conduct must first establish by clear and convincing evidence that there was a material misrepresentation or omission of information, and then establish a threshold level of intent on the part of the applicant. *See also Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577–78, 224 USPQ 409, 414–15 (Fed. Cir. 1984).

Our major standard for materiality is whether a reasonable examiner would consider the omission or misrepresentation important in deciding whether to issue the patent.[14] Materiality and intent must also be considered together: the more material the omission or misrepresentation, the less intent that must be shown to reach a conclusion of inequitable conduct. *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1363, 220 USPQ 763, 773 (Fed. Cir.), *cert. denied*, 469 U.S. 821, 224 USPQ 520 (1984).

We uphold the Commission's findings and conclusion that Du Pont's affidavit or arguments before the examiner did not constitute material misrepresentation. As Akzo concedes, the examiner had both the Morgan '645 patent and the Kwolek '542 patents before him throughout the examination process. It was on the basis of these two patents that Du Pont's first three applications were rejected. The mere fact that Du Pont attempted to distinguish the Blades process from the prior art does not constitutes a material omission or misrepresentation. The examiner was free to reach his own conclusion regarding the Blades process based on the are in front of him. Nor does Du Pont's affidavit, advocating a particular interpretation of the Morgan '645 and Kwolek '542 patents (albeit favorable to Du Pont's position), show any intent to mislead the PTO. Du Pont's intent was not to mislead, but rather to distinguish prior art from the Blades process and demonstrate to the examiner that the Blades process and demonstrate to the examiner that the Blades process would not have been obvious in light of Morgan '645 and Kwolek '542. The sum of it is that, because we cannot see either a proved material misrepresentation or a proved intent to mislead, we must conclude that Akzo has not met its burden of proving inequitable conduct before the PTO

III. *Due Process and Treaty Rights*

A. *Due Process.* This aspect of the appeal concerns the Commission's procedures with respect to the private parties' confidential information. On May 21, 1984, the ALJ issued an administrative protective order pertaining to confidential business information, as defined in the Commission's Rules, 19 C.F.R. §210.30(d)(7) (1976), that would be produced during the discovery phase of the investigation.

In general, this order permitted access to all such confidential information by Akzo's and Du Pont's outside counsel but not by management personnel or in-house counsel of either private company. At a preliminary conference held June 22, 1984, Akzo made the first of three unsuccessful attempts to modify the protective order. Arguing that there was a substantial overlap between the Commission's investigation and an action brought by Akzo against Du Pont them (and still) pending in the United States District Court for the District of Delaware, Akzo moved to align the protective orders by modifying the ALJ's protective order so that its terms coincided with those of a protective order earlier issued by the District Court in the Delaware action. The ALJ denied Akzo's motion on July 6, 1984.

By letter dated June 27, 1984, Akzo requested that the protective order be amended

[13] Appellants cite this court's opinion in *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778–79 (Fed. Cir. 1985), as supporting their contention that the Blades '756 patent was anticipated by the prior art. *Titanium Metals* is easily distinguishable from this case. There, a single reference disclosed a range of alloys including that claimed by appellant. In this case, the Commission found that neither the Morgan '645 patent nor any other prior art reference disclosed the Blades '756 process.

[14] This standard is identical to the PTO standard of materiality. 37 C.F.R. §1.56(a).

to include three designated members of Akzo's in-house counsel. On July 6, 1984, the ALJ concluded that Akzo failed to demonstrate the requisite need to warrant granting Akzo's in-house counsel access to Du Pont's confidential business information. Akzo renewed its motion to modify the protective order n February 8, 1985, this time urging that both Akzo's in-house counsel and the general manager of Akzo's Industrial Fiber Group should be granted limited access to Du Pont's confidential business information. Because Akzo failed (in the ALJ's view) to demonstrate a need for either its in-house counsel or its general manager to have access to the requested confidential material, the ALJ denied Akzo's motion on February 21, 1985.

Akzo now contends that the protective order, issued by the ALJ on May 21, 1984, effectively deprived it of its rights to confrontation, to rebuttal, and to effective assistance of counsel. According to Akzo, under the terms of the protective order, the parties' designation of materials as confidential had the effect of "unilaterally immunizing them from scrutiny by the opposing party." Moreover, Akzo maintains that the system established by the protective order completely denied Akzo "access to all of the critical evidence on which the decision against it was based."

[2] Our examination of the challenged protective order, as it was enforced, shows Akzo's charges to be groundless. The protective order provides, *inter alia*, that confidential business information "shall be disclosed at any hearing only *in camera* before the commission or the administrative law judge." Although the protective order enabled either party to designate business information as confidential, such a designation did not "unilaterally immunize" purportedly confidential documents from scrutiny by the opposing party. In the first place, all the protected information was freely available to outside counsel who could fully consider it, although they were not free to show or repeat it to Akzo's management or in-house counsel. Second, paragraph 10 of the protective order provided a mechanism by which either party was free to object to its adversary's designations at any stage of the proceeding. According to paragraph 10, if either party disagreed with respect to the designation of business material as confidential, that party "shall confer [with the supplier] as to the status of the subject information proffered within the context of this order." In the event that the parties failed within 10 days to reach agreement as to the proper status of the information, the protective order provided that either party could submit the issue to the ALJ or the Commission for resolution. The mechanism of paragraph 10 could also be used to permit disclosure to particular persons of otherwise classified material. Although, as mentioned earlier, Akzo attempted to modify the protective order on three separate occasions, Akzo never invoked the dispute resolution procedures of paragraph 10 to challenge Du Pont's characterization of business information as confidential or as not disclosable to particular individuals. Third, the protective order expressly permitted other exceptions to be made by the ALJ or the Commission.

In denying Akzo's various motions to amend the protective order, the ALJ relied on the Commission's decision in *Certain Rotary Wheel Printers*, Inv. No. 337-TA-145, 5 ITRD 1933 (Nov. 4, 1983). According to *Rotary Wheel Printers*:

> [p]rotection of confidential information is crucial to the Commission's ability to carry out its statutory responsibilities. In addition, review after discovery and the evidentiary hearing are completed would provide an inadequate remedy. The inappropriate release of confidential information can never be fully remedied.
>
> The Commission has traditionally been reluctant to release confidential information where not absolutely necessary.

5 ITRD at 1935.

Thus, implicit in Akzo's due process attack on the protective order is the position that, in the interests of fundamental fairness, it was "absolutely necessary" for Akzo's in-house counsel and general manager to have access to Du Pont's confidential business information. However, "[i]n section 337 investigations, it is the exception rather than the rule to release confidential information to in-house counsel." *Id.*

The primary justification for the Commission's reluctance to grant adversary management and in-house counsel access to confidential business information is that, in order to discharge its statutory responsibilties within the strict statutory time limits, the Commission is heavily dependent on the voluntary submission of information. Disclosure of sensitive materials to an adversary would undoubtedly have a chilling effect on the parties' willingness to provide the confidential information essential to the Commission's fact-finding processes. the Commission has resolved the difficult and controversial question of the role of in-house counsel by taking a conservative position on the side of optimum shielding of business information. Obviously, where confidential material is disclosed to an employee of a competitor, the risk of the competitor's obtaining an unfair business advantage may be substantially increased. This general Commission position is neither unreasonable nor arbitrary. It represents an approrpriate balancing between the needs demanded by the Commission's process and the parties' need for participation by its in-house personnel.

This is especially true because there is no *per se* rule against disclosure to either a competitor's in-house counsel or management representative. *Rotary Wheel Printers* established, and the ALJ employed, a three-part balancing test to determine whether, to whom, and under what conditions to release confidential information. Factors to be considered include the party's need for the confidential information sought in order to adequately prepare its case, the harm that disclosure would cause the party submitting the information, and the forum's interest in maintaining the confidentially of the information sought. 5 ITRD at 1937.

After reviewing the record, the ALJ concluded that Akzo failed to demonstrate clearly a need for granting access to confidential business information to either Akzo's in-house counsel or key management officials. The ALJ also found that disclosure would cause substantial harm to Du Pont's competitive position. These particular rulings cannot be faulted. The court understands that all information relating to patent validity and enforceability *(see* Part II, *supra)* was promptly made fully available to all. As for the information bearing on the important question of whether Akzo's importation of aramid fibers would tend to destroy or substantially injure Du Pont's business *(see* Part IV, *infra)*, it is obvious that that confidential information — relating to Du Pont's business, activities, plans and expectations — should not be made available (unless, perhaps, where absolutely necessary for a fair hearing) to a direct competitor like Akzo. That such full access was not absolutely necessary to appellants' making of their own case is shown by the crucial fact that Akzo was at all times perfectly free to offer its own market projections as well as to reveal its own activities, forecasts, and interpretations. Both sides could present to the Commission their own information on those matters without knowing those of the other side's.

Akzo argues, however, that the denial of its motions to modify the protective order effectively denied its due process right to participate in its own defense. The contention is that Akzo was subjected to serious adverse governmental action on the basis of evidence which Akzo was never permitted to know and "personally" refute. In support of this position, Akzo invokes §555(b) of the Administrative Procedure Act which was made applicable to §337 proceedings by the 1974 Amendments to the Tariff Act of 1930. Under §555(b), "[a] party is entitled to appear in person or by or with counsel or other duly qualified representative in an agency proceeding." 5 U.S.C. §555(b). However, Akzo was represented by competent and experienced outside counsel throughout the proceedings; these counsel were aware of all confidential information. Further, Akzo fails to recognize that "the affirmative grant of the right to appear apparently bestowed by Section 555(b) is not blindly absolute, without regard to the status or nature of the proceedings and concern for the orderly conduct of public business." *DeVyver v. Warden, U.S. Penitentiary*, 388 F.Supp. 1213, 1222 (M.D. Pa. 1974) citing *Easton Utilities Commission v. Atomic Energy Commission*, 424 F.2d 847, 852 (D.C. Cir. 1970). Whatever else §555(b) guarantees to parties to an administrative proceeding under §337, it does not mandate disclosure of significant confidential information to in-house counsel and corporate executives of a business competitor — where that information is fully available to outside counsel. Akzo's contention withers in the face of unrefuted evidence that more than 90 people representing Akzo, including numerous expert witnesses and members of the battery of four law firms comprising Akzo's defense team, had unrestricted access to Du Pont's confidential information.

Akzo has also failed to demonstrate that it suffered actual harm under the confidentiality procedures instituted by the ALJ. Although Akzo's insiders were denied access to Du Pont's economic and market forecasts with respect to the production and sale of aramid fibers, Akzo was not prevented (as we have pointed out) from offering its own projections into evidence under the cover of confidentiality. It is difficult to see how Akzo was prejudiced.

Finally, we have neither found nor been directed to any judicial decision in this country mandating, in the circumstances present here, that business confidential information *must* be made to inside management. On the contrary, we are aware, from the practice of our own court, that records in appeals to us are frequently classified in large part, and are presumably not available to the management of the opposing party. Moreover, there are a substantial number of decisions uphold-

ing confidentiality comparable to that accepted by the Commission. Akzo tells us that most of these involved only pretrial discovery (and not evidence at a hearing or trial) and that the others are also distinguishable. We do not stop to examine these arguments because, at the least, these decisions (a) show that there is no holding to the contrary of the one we now make and (b) strongly suggest the validity of carefully tailored protective orders allowing exceptions to be made if adequate proof is made.[15]

B. *Treaty rights.* As an alternate ground for reversal, Akzo argues that, because the proceedings below discriminated against Akzo on the basis of its Dutch nationality, they violate United States treaty obligations. We disagree with Akzo's premise that there was discrimination here. Essentially, Akzo employs a *non sequitur* to support its position. The core of Akzo's claim is that it was denied the rights that would have been afforded a domestic firm sued for patent infringement in a district court. According to Akzo, this "inferior treatment" by the Commission constitutes discrimination on the basis of nationality. That analysis misses the mark. The appropriate inquiry is whether Akzo was afforded the same rights afforded to domestic firms in a *§337 proceeding* before the *Commission*. Clearly, Akzo has failed to demonstrate that it suffered from discriminatory treatment. First, under the express terms of the protective order, both Akzo and Du Pont were bound by identical procedures regarding confidentiality and discovery. Neither party was allowed access to the other party's confidential business information. Second, the same argument was rejected in *Certain Spring Assemblies and Components Thereof*, Inv. No. 337-TA-88, 216 USPQ 225, *aff'd sub nom. General Motors Corp. v. U.S. International Trade Commission*, 687 F.2d 476, 215 USPQ 484 (CCPA 1982), *cert. denied*, 459 U.S. 1105 (1983). In that case, respondent unsuccessfully raised certain U.S.-Canadian treaties as a defense to enforcement of §337. The Commission observed:

> Section 337 does not discriminate against foreign corporations by virtue of their foreign status. It applies to foreign and domestic corporations alike. Section 337 gives the Commission jurisdiction over products imported from a foreign country, *even if they are manufactured and/or imported by a U.S. corporation.* The Commission's jurisdiction lies in unfair acts occurring in connection with the importation of goods into the United States or their sale, and it extends to all persons engaged in such unfair acts.

216 USPQ at 231 (emphasis added).

IV. *Other Issues*

In this part we consider four separate issues raised by appellants: (1) whether the Commission properly found that continued importation of Akzo's product would substantially injure or tend to injure Du Pont; (2) whether adjudication of §337 actions by a non-Article III tribunal is unlawful; (3) whether Du Pont's pricing practices (with respect to its aramid products) violate the antitrust laws; and (4) whether Du Pont committed inequitable conduct by infringing Akzo's own patent.

A. *Tendency to destroy or substantially injure.* The ALJ concluded (and we have upheld) that Akzo violated §337(a) by the unlawful importation or sale of certain aramid fibers produced in the Netherlands by means of a process which if practiced in the United States would infringe the Blades '756 patent. Such acts, long considered to be violative of §337, clearly constitute unfair acts for the purposes of the statute. *See, e.g., In re Chain Door Locks*, USITC Pub. No. 770 (Apr. 1976), 191 USPQ 272 (USITC 1976); *In re Von Clemm*, 229 F.2d 441, 108 USPQ 371 (CCPA 1955); *In re Amtorg Trading Corp.*, 75 F.2d 826, 24 USPQ 315 (CCPA), *cert. denied*, 296 U.S. 576 (1935).

However, unfair acts, without more, are legally insufficient to support a finding of a §337 violation. That provision declares unlawful "[u]nfair methods of competition and unfair acts in the importation of articles . . ., the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States." Thus, to prove a violation of §337, the complainant must show both an unfair act and a resulting detrimental effect or tendency. *New England Butt Co. v. U.S. International Trade Commission*, 756 F.2d 874, 876, 225 USPQ 260, 261 (Fed. Cir. 1985). As this court recently held in *Textron, Inc. v. U.S. International Trade Commission*, 753 F.2d 1019, 224 USPQ 625 (Fed. Cir. 1985), "section 337 has consistently been interpreted to contain a distinct injury requirement of independent proof." 753 F.2d at 1028, 224 USPQ at 631 (citations omitted); *accord, Corning Glass Works v. U.S. International Trade Commission*, 799 F.2d 1559, 230 USPQ 822 (Fed. Cir. 1986); *Warner Brothers, Inc. v. U.S. International Trade Commission*, 787 F.2d 562, 564, 229 USPQ 126, 127 (Fed. Cir. 1986).

According to *Textron*, "Congress may well have included this separate requirement . . . to insure that the extreme and internationally provocative remedy contemplated [by §337] — exclusion of imports from particular countries — would be implemented only when this is compelled by strong economic reasons." 753 F.2d at 1028–29, 224 USPQ at 631 (citations omitted). It follows that the mere concurrence of an unfair act and some resulting injury is not necessarily sufficient, in itself, to establish a violation of §337. "Congress has directed that the remedy of section 337, involving as it does the act of the sovereign in closing our borders to certain imports, be exercised only in those instances where at least there is proof of a tendency to *substantially* injure the subject industry." *Corning Glass Works v. U.S. International Trade Commission*, 799 F.2d 1559, 1567, 230 USPQ 822, 827 (Fed. Cir. 1986) (emphasis in original).

Not only is an injury determination intimately wed to the particular facts of each case, but also the determination of injury is precisely the type of question which Congress has committed to the expertise of the Commission. Thus, on appeal, our review of an injury determination is limited to deciding whether the Commission's decision is supported by substantial evidence. 19 U.S.C. §1337(c) (1982); 5 U.S.C. §706 (1982); *SSIH Equipment S.A. v. U.S. International Trade Commission*, 718 F.2d 365, 371, 218 USPQ 678, 684 (Fed. Cir. 1983); *General Motors Corp. v. U.S. International Trade Commission*, 687 F.2d 476, 215 USPQ 484 (CCPA 1982), *cert. denied*, 459 U.S. 1105 (1983). In other words, we must decide "whether substantial evidence supports the facts relied on and whether the Commissioner's [sic] determination, on the record, is arbitrary, capricious, or an abuse of discretion." *Corning Glass Works*, 799 F.2d at 1568, 230 USPQ at 828. As we noted in *Corning Glass Works*, "the question of quantum of injury is not one on which it would be appropriate for this court to put forth a legal standard." *Id.* Nor are we allowed to substitute our own judgment for that of the Commission. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). Of course, a decision is supported by substantial evidence if it is supported by "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

Our review of the record in this case compels the conclusion that the Commission's determination — that Akzo's unfair imports of aramid fibers will have a tendency to injure Du Pont substantially — is supported by substantial evidence. The Commission based its injury determination on a prediction of the future effect of Akzo's unfair imports on the domestic industry. There is substantial support for this determination. The record reflects Akzo's intent and capacity to enter the United States aramid fibers market, Du Pont's resulting loss of revenue, and a probable price reduction by Du Pont in response to Akzo's entry into the United States market. Nonetheless, Akzo urges this court to overturn the Commission's exclusion order and deny relief to Du Pont. Akzo first contends that its projected share of the U.S. market during the remaining life of the '756 patent is *de minimis*. It would be both unwise and improper for this court to establish some arbitrary market-share benchmark as a prerequisite to a finding of a §337 violation and we decline to do so. It is sufficient that the record supports the Commission's conclusion that, upon entry into the U.S. market, Akzo will capture a significant share of the domestic market, if not in relative percentage figures than certainly in absolute dollar figures.

[3] Second, Akzo maintains that, notwithstanding its entry into the market, Du Pont's aramid fibers sales volume, revenues and profits will all increase during the remaining life of the patent. But Akzo mischaracterizes the proper standard for measuring injury. The issue is not whether Du Pont's sales, revenues and profits will increase beyond their 1985 levels but rather whether Akzo's presence in the market will substantially injure Du Pont's business during the 1986 – 1990 period (the remaining life of the Blades '756 patent).

As Du Pont correctly points out, nothing in §337 requires a showing that the domestic industry will be utterly deprived of profitability. "Where the unfair practice is the importation of products that infringe a domestic industry's . . . patent right, even a relatively small loss of sales may establish, under section 337(a), the requisite injury . . . ." *Bally/Midway Mfg. Co. v. U.S. International Trade Commission*, 714 F.2d 1117, 1124, 219 USPQ 97, 102 (Fed. Cir. 1983). This proposition is entirely consistent with the legislative history of §337. In a House

[15] This case differs from *Viscofan S.A. v. U.S. International Trade Commission*, 787 F.2d 544, 552, 229 USPQ 118, 124 (Fed. Cir. 1986), because here (but not in *Viscofan*) the confidentiality problem was directly related to the propriety of the exclusion order. Accordingly, we have reviewed the merits of the confidentiality actions. *See American Telephone and Telegraph Co. v. U.S. International Trade Commission*, 626 F.2d 841, 842, 206 USPQ 111, 112 (CCPA 1980).

Report discussing the application of §337 to unfair competition involving patent infringement, Congress stated: "Where unfair methods and acts have resulted in *conceivable losses of sales*, a tendency to substantially injure such industry has been established." *See* House Comm. on Ways and Means, Trade Reform Act of 1973, H.R. Rep. No. 571, 93d Cong. 1st Sess. 78 (1973) (emphasis added); *accord In re Von Clemm*, 229 F.2d 441, 445, 108 USPQ 371, 374 (CCPA 1955).

Because substantial evidence supports the facts relied upon by the Commission in making its determination that Akzo's unfair imports would tend to injure Du Pont substantially, we must affirm its injury determination. Akzo has failed to demonstrate that the commission's determination is arbitrary, capricious, or an abuse of discretion.

A contrary result would emasculate the protections of §337 with respect to high technology ventures. Typically, in high technology industries, acute competition forces competitors to commit substantial resources to research and development in hopes of generating profits before either their patents expire or before technological advance makes the products obsolete. Thus, innovators frequently resign themselves to losses during the early life of their patents with the expectation that, if product development and marketing efforts are successful, profits earned during the later life of other patents will provide sufficient compensation for their endeavors.

On this record, Du Pont's aramid fibers industry can be said to furnish a classic illustration. Although Du Pont has undertaken extensive product development and marketing efforts since 1973, the company had not earned any return on its investment through 1984. Du Pont anticipates that it will realize its first positive net operating earnings from its aramid fibers production in 1985.

In reaching its injury determination, the Commission permissibly recognized that the aramid fibers industry is in transition from a period requiring extremely high investment of resources to a period when the industry will finally realize a return on that investment. In these circumstances, diminished profits, lower return on investment, and reduced sales are all indicative of substantial injury.

[4] *B. Adjudication of §337 actions by a non-Article III tribunal.* Apparently employing the "kitchen sink" or "let's try anything" approach to appellate advocacy, Akzo raises an additional challenge to the Commission's proceedings. Relying primarily on *Northern Pipeline Construction Co. v. Marathon Pipe Line Co.*, 458 U.S. 50 (1982), Akzo characterizes the current §337 proceedings as "inherently judicial" involving "essentially private rights" and concludes that the Constitution requires adjudication of §337 issues by Article III courts. Both Akzo's premise and conclusion are flawed. Although it is true that private rights may be affected by §337 determinations, the thrust of the statute is directed toward the protection of the public interest from unfair trade practices in international commerce. As this court recognized in *Young Engineers, Inc. v. U.S. International Trade Commission*, 721 F.2d 1305, 1315, 219 USPQ 1142, 1152 (Fed. Cir. 1983), a §337 proceeding "is not purely private litigation 'between the parties' but rather is an 'investigation' by the Government into unfair methods of competition or unfair acts in the importation of articles into the United States." Moreover, "[t]he power to regulate commerce with foreign nations is expressly conferred upon Congress, and being an enumerated power is complete in itself, acknowledging no limitations other than those prescribed in the Constitution." *Buttfield v. Stranahan*, 192 U.S. 470, 492 (1904). Properly viewed, §337 and its predecessor provisions represent a valid delegation of this broad Congressional power for the public purpose of providing an adequate remedy for domestic industries against unfair practices beginning abroad and culminating in importation. *Sealed Air Corp. v. U.S. International Trade Commission*, 645 F.2d 976, 985–86, 209 USPQ 469, 478 (CCPA 1981).

C. Du Pont's pricing practices. Under Du Pont's value-in-use pricing program, the price at which Du Pont sells aramid fibers varies in accordance with the particular end-use to which the purchaser puts the product. Although Du Pont's customers may use the aramid fibers for whatever purpose they desire, they are required to pay Du Pont the price appropriate to the ultimate end-use. To that objective, Du Pont requires its customers to agree that they will use the aramid fibers for the specific end-use for which they are purchased or, if the aramid fibers are put to a different end-use or are resold, that they will pay Du Pont an amount representing the difference between the initial purchase price and the price for the ultimate end-use.

According to Akzo, each such agreement constitutes a "contract ... in restraint of trade," and the entire pattern of agreements, policing and surveillance constitutes a "combination ... in restraint of trade" within the meaning of §1 of the Sherman Act. Although the Commission specifically found that "the adoption of Du Pont's value-in-use pricing strategy reflects price competition with other substitute products for various end uses," Akzo continues to argue that Du Pont's value-in-use pricing for aramid fibers violates the antitrust laws.

Plainly, value-in-use pricing is not *per se* an anticompetitive restraint on trade within the meaning of the antitrust laws. In *Carter-Wallace, Inc. v. United States*, 449 F.2d 1374, 171 USPQ 359 (Ct. Cl. 1971), one of this court's predecessor courts sustained against an antitrust challenge a pricing system in which purchasers paid a lower price for the drug meprobamate when used in certain combination drugs. The court noted that "the vendee firms, if one looks at their business as a whole, are not prohibited or deterred from making any use they wish of the meprobamate." *Id.* at 1379, 171 USPQ at 362. Moreover, "[i]t is even reasonable to assume, nothing else appearing, that if the vendees change their minds after purchasing the drug at the lower price they can make unrestricted use of it by paying the difference between that lower price and the consent-decree price." *Id.* at 1379 n.4, 171 USPQ at 362 n.4.

Similarly, under Du Pont's value-in-use pricing system, its customers may use their aramid fibers for whatever purpose they desire, including resale, providing they pay Du Pont the price appropriate to the ultimate end-use. Contrary to Akzo's position that Du Pont's pricing system is anticompetitive and an unreasonable restriction on use and resale, the Commission found and the record establishes that Du Pont's value-in-use pricing has the procompetitive effect of increasing the volume of aramid fibers that are sold.

Akzo also claims that the ALJ erred in not making specific findings on market definition. But, as this court recently observed, the trier of fact need not engage in the meaningless exercise of market definition where no wrongful conduct has been shown. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 875, 228 USPQ 90, 100 (Fed. Cir. 1985). Equally groundless is Akzo's contention that the ALJ erred by not shifting to Du Pont the burden of demonstrating that is pricing policies had procompetitive effects. The Supreme Court, in *National Collegiate Athletic Ass'n v. Board of Regents*, 468 U.S. 895 (1984), made abundantly clear that the burden of proof shifts only where the evidence shows that the challenged practice has the "hallmarks of anticompetitive behavior," namely, that "it has operated to raise prices and reduce output." *Id.* at 113. Conversely, in this case, the evidence establishes and the Commission found that the alleged "restraint," value-in-use pricing, results in reduced prices and increased output.

D. *Du Pont's alleged inequitable conduct in manufacture.* During the proceedings below, Akzo asserted that Du Pont infringed Akzo's U.S. patent 4,308,374 ('374) patent) on a polymerization solvent system used in the formulation of the polymer which is spun into aramid fibers by means of the Blades '756 process. Notwithstanding §337(c) of the Tariff Act of 1930 which provides that "[a]ll legal and equitable defenses may be presented," the ALJ struck Akzo's equitable defense and refused to hear the underlying evidence. On appeal, Akzo contends that the ALJ thus denied Akzo the opportunity to establish a meritorious defense to Du Pont's §337 claim. For two reasons we disagree that this defense was meritorious.

Our conclusion is first supported by the recent decision of the District Court for the Eastern District of Virginia holding the '374 patent invalid for obviousness under 35 U.S.C. §103. *Akzo N.V. v. E.I. DuPont de Nemours & Co.*, Civil Action No. 85-0459-R (E.D. Va. April 24, 1986), on appeal to this court, No. 86-1327/1358.[16] Under that decision, Akzo's infringement claim has been adversely decided and Du Pont has a legal right to do the act claimed to be infringing. Consequently, there is as yet no legitimate basis for Akzo's equitable defense. *See Young Engineers, Inc. v. U.S. International Trade Commission*, 721 F.2d 1305, 1315–16, 219 USPQ 1142, 1152 (Fed. Cir. 1983). Second, this same result is compelled in this instance by this court's decision in *SSIH Equipment S.A. v. U.S. International Trade Commission*, 718 F.2d 365, 218 USPQ 678 (Fed. Cir. 1983). In *SSIH*, we held that allegedly "inequitable conduct" is not a defense to a §337 action where the conduct occurred after issuance of the complainant's patent and involved a different patent. *Id.* at 378–79, 218 USPQ at 689–90. In this case, Du Pont's '756 patent was issued in 1973 and pertains to a spinning process; Akzo's '374 patent was issued in 1981 and pertains to a polymerization process.

Conclusion

For these reasons, we affirm the Commission's exclusion order prohibiting the impor-

[16] That appeal was argued on November 7, 1986 before the same panel of judges as heard the current appeal.

tation into the United States of aramid fibers manufactured by Akzo in the Netherlands. *AFFIRMED.*

Court of Appeals, Ninth Circuit

Lifshitz v. Walter Drake & Sons Inc., et al.

Nos. 85-6087 and 85-6130

Decided December 30, 1986

JUDICIAL PRACTICE AND PROCEDURE

1. Procedure — Motions (§410.31)

F.R.Civ.P. 50(b)'s requirement that motion for judgment notwithstanding verdict be brought only if party has moved for directed verdict at close of evidence is not satisfied by defendant's motion in limine which, in seeking dismissal of plaintiff's unfair competition claims, was brought prior to trial but not ruled upon until after close of evidence, which was limited to claim that court lacked jurisdiction to entertain common law unfair competition claims based on alleged copying, and which did not address additional unfair competition issues, since issue of sufficiency of evidence on unfair competition claims was not placed squarely before district court, and thus such motion was not enough like motion for directed verdict so as to satisfy requirements of rule.

COPYRIGHTS

2. Notice, deposit and registration — Notice — Omission of or error in notice (§207.0305)

Copyright Act's exception, 17 USC 405(a)(1), for distribution of "relatively small" number of copies of work from which copyright notice has been omitted, does not apply in case where party began adding copyright notice with date more than one year after year in which first publication occurred, since all copies of such work, numbering approximately 15,000, are deemed by 17 USC 406(b) to have been published without notice.

3. Notice, deposit and registration — Notice — Omission of or error in notice (§207.0305)

Copies of product not bearing copyright notice that were in hands of distributor had not yet been "distributed to the public" as called for by 17 USC 405(a)(2), and thus party asserting copyright should have made efforts to remedy notice on such copies.

4. Notice, deposit and registration — Notice — Omission of or error in notice (§207.0305)

"Substantial compliance rule," which has been applied under 1909 Copyright Act to bar willful infringers from asserting errors in copyright notice as defense, should not be applied to significantly different statutory scheme of 1976 Copyright Act.

Appeal from District Court for the Central District of California, Keller, J.

Actions by Igor Lifshitz against Walter Drake & Sons Inc., and Etna Products Co. Inc. for trademark infringement, unfair competition, fraud, conspiracy, copyright infringement, and intentional infliction of emotional distress. From judgment in part for plaintiff, defendant Etna and plaintiff appeal. Affirmed.

Kathryn Tschopik, Los Angeles, Calif., and Robert C. Faber, New York, N.Y., for appellant.

Clinton T. Bailey, Beverly Hills, Calif., for appellee Lifshitz.

Before Wallace, Boochever, and Kozinski, Circuit Judges.

Wallace, Circuit Judge.

Etna Products Co., Inc. (Etna) appeals from the district court's denial of its motion for a judgment notwithstanding the verdict (j.n.o.v.) or for a new trial on Lifshitz's unfair competition claim. Etna also contends that the district court erred in denying its motion for a new trial because of improper instruction to the jury regarding Lifshitz's unfair competition claims, and in improperly excluding certain evidence. Lifshitz cross-appeals from the entry by the district court of a j.n.o.v. on Lifshitz's copyright claim. The district court had jurisdiction under 28 U.S.C. §§ 1332 and 1338(b). We have jurisdiction pursuant to 28 U.S.C. § 1291, and we affirm.

I

Lifshitz, a native of the Soviet Union who emigrated to the United States in 1975, developed a mechanical device for making hors d'oeuvres that he began marketing to the general public in 1979. By 1981, Lifshitz had also sold his hors d'oeuvres maker to two mail order houses and was seeking to market it to several others, including Walter Drake & Sons, Inc. (Drake). In response to Lifshitz's efforts, Drake requested additional information and a sample of the device. Drake subsequently informed Lifshitz that it intended to include his product in its next catalogue. Ultimately, however, Drake purchased an apparently identical product from Etna and began to market it instead. In the latter part of 1982, Lifshitz learned that this replica was being advertised in Drake's 1982 Christmas catalogue and instituted this action against Etna and Drake, as well as several other mail other companies. The action was subsequently dismissed against all parties except Etna and Drake.

Lifshitz pleaded a wide variety of claims but pretrial motions and dismissals pared the issues substantially. The case was submitted to the jury on claims for trademark infringement, unfair competition, fraud, conspiracy, copyright infringement, and intentional infliction of emotional distress. The jury found in favor of Drake on all claims, and against Etna on only the unfair competition and copyright infringement claims. Etna then moved for a j.n.o.v. and for a new trial. The district court granted Etna's motion for a j.n.o.v. with respect to Lifshitz's copyright claim, but denied it with respect to Lifshitz's unfair competition claim, and denied Etna's motion for a new trial.

Etna appealed the denial of its j.n.o.v. motion with regard to the unfair competition claim and of its motion for a new trial. Lifshitz cross-appealed the j.n.o.v. in favor of Etna on the copyright infringement claim.

II

We treat first Etna's appeal from the district court's denial of its motions for a j.n.o.v. on Lifshitz's unfair competition claims and for a new trial.

In order to bring a motion for j.n.o.v., a party must have moved for a directed verdict at the close of all the evidence. Fed. R. Civ. P. 50(b). The motion Etna filed for a directed verdict after the close of evidence in the trial below requested a directed verdict only on Lifshitz's copyright and trademark claims. It did not address Lifshitz's unfair competition claims. Etna does not dispute this but rather asserts that the requirement of rule 50(b) is satisfied by its pretrial motion *in limine* for dismissal of Lifshitz's unfair competition claims. Although brought before trial, the district court did not rule on this motion until after further discussions with the parties following the close of evidence.

We observe strictly the threshold requirement for a j.n.o.v. that a motion for a directed verdict must be made at the close of all the evidence. *Farley Transportation Co. v. Santa Fe Trail Transportation Co.*, 786 F.2d 1342, 1346 (9th Cir. 1985) (*Farley*). The answer to the question before us, however, is determined by identifying what may be considered a sufficient motion for a directed verdict at the close of evidence for purposes of rule 50(b). *Id.* at 1347. In *Bachtel v. Mammoth Bulk Carriers, Ltd.*, 605 F.2d 438, 441–42 (9th Cir. 1979), *cert. granted and judgment vacated on other grounds*, 451 U.S. 978 (1981), we held that a motion for a directed verdict at the close of plaintiff's evidence coupled with a request after the close of all the evidence for an instruction requiring the jury to return a verdict in the defendant's favor satisfied the requirements of rule 50(b). We stated that "[t]hese procedural steps placed the issue of the sufficiency of the evidence before the court [at the end of the case]." *Id.* at 441–42. Our inquiry must therefore focus on whether Etna's motion *in limine* and the subsequent colloquy with and ruling by the district judge following the close of evidence squarely placed the issue of the sufficiency of the evidence before the district court so we can say it was enough like a motion for a directed verdict that it satisfied the requirements of rule 50(b).

How much latitude we have in making this determination is governed by the reasons for the requirement. The motion for a directed verdict required by rule 50(b) as a prerequisite for a j.n.o.v. serves two important purposes. The first is to preserve the sufficiency of the evidence as a question of law. A subsequent motion for a j.n.o.v. will then allow the district court to reexamine its decision not to direct a verdict as a matter of law rather than to engage in an impermissible reexamination of facts found by the jury. *Ohio-Sealy Mattress Manufacturing Co. v. Sealy, Inc.*, 585 F.2d 821, 825 [200 USPQ 337, 339] (7th Cir. 1978), *cert. denied*, 440 U.S. 930 [201 USPQ 256] (1979). The second purpose of a motion for a directed verdict is to call the claimed deficiency in the evidence to the attention of the court and to opposing counsel at a time when the opposing party is still in a position to correct the deficit. *Quinn v. Southwest Wood Products, Inc.*, 597 F.2d 1018, 1025 (5th Cir. 1979). These purposes are served when a party,

APPENDIX 'G'

products so that they can be positioned to enter the general market at the end of the lives of relevant patents. At least for relatively small start-up companies like Ventritex, where much of the business and technical work essential to survival is done by a small group of people, the promise by Congress of a safe haven could prove to be completely illusory if the courts permitted competitors to proceed full bore with expensive, resource-draining, and personnel-distracting litigation in the form of actions for declaratory relief. It makes little sense, and thus we assume would be inconsistent with Congress' intent, to protect companies like Ventritex from suit for actual patent infringement but leave them fully exposed to declaratory relief actions whose gravamen and burdens are much the same. While the considerations discussed in the preceding paragraph are sufficient to support our decision not to exercise jurisdiction at this time over plaintiff's declaratory relief counts, the fact that these additional policy considerations cut in the same direction intensifies our resolve.

For all the reasons discussed in this section, we hereby GRANT defendants' motion to dismiss plaintiff's declaratory relief claims (Counts VIII and IX). Those Counts are ORDERED dismissed.

V. DEFENDANTS' MOTION TO DISMISS THE REMAINING STATE LAW CLAIMS (COUNTS X - XIX).

Defendants earlier moved this court to dismiss plaintiff's state law claims asserted in Counts X - XVII of plaintiff's original complaint. Defendants contended that, since the sole basis of subject matter jurisdiction over these claims was pendency to the federal question claims in Counts I - IX, the court should dismiss the state law claims if it grants defendants' motion to dismiss the federal law claims in counts I - IX.

However, plaintiff has since amended its complaint. The second amended complaint now alleges a separate basis for jurisdiction under 28 U.S.C. § 1332(a) (diversity). Plaintiff also has added two new counts, including an additional federal claim (Count XVIII — Correction of Inventorship) that is not disposed of by our ruling on the applicability of the 271(e)(1) defense. Thus, we hereby DENY defendants' motion to dismiss plaintiff's state law claims.

VI. CONCLUSION.

Given the dispositive effect of the 271(e)(1) defense on Counts I - IX of plaintiff's second amended complaint, this court finds that there is no just reason for delaying final judgment on those counts, despite the remaining federal law count and the state law counts. Thus, we ORDER entry of summary judgment on Counts I - IX.

IT IS SO ORDERED.

Court of Appeals, Federal Circuit

In re Vaeck

No. 91-1120

Decided October 21, 1991

PATENTS

1. Patentability/Validity — Obviousness — Combining references (§115.0905)

Rejection of claimed subject matter as obvious under 35 USC 103 in view of combination of prior art references requires consideration of whether prior art would have suggested to those of ordinary skill in art that they should make claimed composition or device, or carry out claimed process, and whether prior art would also have revealed that such person would have reasonable expectation of success; both suggestion and reasonable expectation of success must be founded in prior art, not in applicant's disclosure.

2. Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Patent and Trademark Office has failed to establish prima facie obviousness of claims for use of genetic engineering techniques for producing proteins that are toxic to insects such as larvae of mosquitos and black flies, since prior art does not disclose or suggest expression in cyanobacteria of chimeric gene encoding insecticidally active protein, or convey to those of ordinary skill reasonable expectation of success in doing so; expression of antibiotic resistance-conferring genes in cyanobacteria, without more, does not render obvious expression of unrelated genes in cyanobacteria for unrelated purposes.

3. Patentability/Validity — Specification — Enablement (§115.1105)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Judicial review — Standard of review — Patents (§410.4607.09)

Specification must, in order to be enabling as required by 35 USC 112, first paragraph, teach person skilled in art to make and use

invention without "undue experimentation," which does not preclude some experimentation; enablement is question of law which is reviewed independently on appeal, although such determination is based upon underlying factual findings which are reviewed for clear error.

PATENTS

4. Patentability/Validity — Specification — Enablement (§115.1105)

Patent and Trademark Office did not err in rejecting, as non-enabling pursuant to 35 USC 112, first paragraph, claims for use of genetic engineering techniques for producing proteins that are toxic to insects such as larvae of mosquitos and black flies, in view of relatively incomplete understanding of biology of cyanobacteria as of applicants' filing date, as well as limited disclosure by applicants of particular cyanobacterial genera operative in claimed invention, since there is no reasonable correlation between narrow disclosure in applicants' specification and broad scope of protection sought in claims encompassing gene expression in any and all cyanobacteria.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent, serial no. 07/021,405, filed March 4, 1987, by Mark A. Vaeck, Wipa Chungjatupornchai, and Lee McIntosh (hybrid genes incorporating a DNA fragment containing a gene coding for an insecticidal protein, plasmids, transformed cyanobacteria expressing such protein and method for use as a biocontrol agent). From decision rejecting claims 1-48 and 50-52 as unpatentable under 35 USC 103, and rejecting claims 1-48 and 50-51 for lack of enablement, applicants appeal. Affirmed and part and reversed in part; Mayer, J., dissents with opinion.

Ian C. McLeod, Okemos, Mich., for appellant.

Teddy S. Gron, associate solicitor (Fred E. McKelvey, solicitor and Richard E. Schafer, associate solicitor, with him on brief), for appellee.

Before Rich, Archer, and Mayer, circuit judges.

Rich, J.

This appeal is from the September 12, 1990 decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), affirming the examiner's rejection of claims 1-48 and 50-52 of application Serial No. 07/021,405, filed March 4, 1987, titled "Hybrid Genes Incorporating a DNA Fragment Containing a Gene Coding for an Insecticidal Protein, Plasmids, Transformed Cyanobacteria Expressing Such Protein and Method for Use as a Biocontrol Agent" as unpatentable under 35 USC 103, as well as the rejection of claims 1-48 and 50-51 under 35 USC 112, first paragraph, for lack of enablement. We reverse the § 103 rejection. The § 112 rejection is affirmed in part and reversed in part.

BACKGROUND

A. *The Invention*

The claimed invention is directed to the use of genetic engineering techniques [1] for production of proteins that are toxic to insects such as larvae of mosquitos and black flies. These swamp-dwelling pests are the source of numerous human health problems, including malaria. It is known that certain species of the naturally-occurring *Bacillus* genus of bacteria produce proteins ("endotoxins") that are toxic to these insects. Prior art methods of combatting the insects involved spreading or spraying crystalline spores of the insecticidal *Bacillus* proteins over swamps. The spores were environmentally unstable, however, and would often sink to the bottom of a swamp before being consumed, thus rendering this method prohibitively expensive. Hence the need for a lower-cost method of producing the insecticidal *Bacillus* proteins in high volume, with application in a more stable vehicle.

As described by appellants, the claimed subject matter meets this need by providing for the production of the insecticidal *Bacillus* proteins within host cyanobacteria. Although both cyanobacteria and bacteria are members of the procaryote [2] kingdom, the

[1] Basic vocabulary and techniques for gene cloning and expression have been described in *In re O'Farrell*, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir. 1988), and are not repeated here.

[2] All living cells can be classified into one of two broad groups, procaryotes and eucaryotes. The procaryotes comprise organisms formed of cells that do not have a distinct nucleus; their DNA floats throughout the cellular cytoplasm. In contrast, the cells of eucaryotic organisms such as man, other animals, plants, protozoa, algae and yeast have a distinct nucleus wherein their DNA resides.

cyanobacteria (which in the past have been referred to as "blue-green algae") are unique among procaryotes in that the cyanobacteria are capable of oxygenic photosynthesis. The cyanobacteria grow on top of swamps where they are consumed by mosquitos and black flies. Thus, when *Bacillus* proteins are produced within transformed [3] cyanobacterial hosts according to the claimed invention, the presence of the insecticide in the food of the targeted insects advantageously guarantees direct uptake by the insects.

More particularly, the subject matter of the application on appeal includes a chimeric (i.e., hybrid) gene comprising (1) a gene derived from a bacterium of the *Bacillus* genus whose product is an insecticidal protein, united with (2) a DNA promoter effective for expressing [4] the *Bacillus* gene in a host cyanobacterium, so as to produce the desired insecticidal protein.

The claims on appeal are 1-48 and 50-52, all claims remaining in the application. Claim 1 reads:

> 1. A chimeric gene capable of being expressed in Cyanobacteria cells comprising:
> (a) a DNA fragment comprising a promoter region which is effective for expression of a DNA fragment in a Cyanobacterium; and
> (b) at least one DNA fragment coding for an insecticidally active protein produced by a Bacillus strain, or coding for an insecticidally active truncated form of the above protein or coding for a protein having substantial sequence homology to the active protein,
> the DNA fragments being linked so that the gene is expressed.

Claims 2-15, which depend from claim 1, recite preferred *Bacillus* species, promoters, and selectable markers.[5] Independent claim 16 and claims 17-31 which depend therefrom are directed to a hybrid plasmid vector which includes the chimeric gene of claim 1. Claim 32 recites a bacterial strain. Independent claim 33 and claims 34-48 which depend therefrom recite a cyanobacterium which expresses the chimeric gene of claim 1. Claims 50-51 recite an insecticidal composition. Claim 52 recites a particular plasmid that appellants have deposited.

B. *Appellants' Disclosure*

In addition to describing the claimed invention in generic terms, appellants' specification discloses two particular species of *Bacillus* (*B. thuringiensis*, *B. sphaericus*) as sources of insecticidal protein; and nine genera of cyanobacteria (*Synechocystis*, *Anacystis*, *Synechococcus*, *Agmenellum*, *Aphanocapsa*, *Gloecapsa*, *Nostoc*, *Anabaena* and *Ffremyllia*) as useful hosts.

The working examples relevant to the claims on appeal detail the transformation of a single strain of cyanobacteria, i.e., *Synechocystis* 6803. In one example, *Synechocystis* 6803 cells are transformed with a plasmid comprising (1) a gene encoding a particular insecticidal protein ("B.t. 8") from *Bacillus thuringiensis* var. *israelensis*, linked to (2) a particular promoter, the P_L promoter from the bacteriophage Lambda (a virus of *E. coli*). In another example, a different promoter, i.e., the *Synechocystis* 6803 promoter for the rubisco operon, is utilized instead of the Lambda P_L promoter.

C. *The Prior Art*

A total of eleven prior art references were cited and applied, in various combinations, against the claims on appeal.

The focus of Dzelzkalns,[6] the primary reference cited against all of the rejected claims, is to determine whether chloroplast promoter sequences can function in cyanobacteria. To that end Dzelzkalns discloses the expression in cyanobacteria of a chimeric gene comprising a chloroplast promoter sequence fused to a gene encoding the enzyme chloramphenicol acetyl transferase (CAT).[7] Importantly, Dzelzkalns teaches the use of the CAT gene as a "marker" gene; this use of antibiotic resistance-conferring genes for selection purposes is a common technique in genetic engineering.

[3] "Transformed" cyanobacteria are those that have successfully taken up the foreign *Bacillus* DNA such that the DNA information has become a permanent part of the host cyanobacteria, to be replicated as new cyanobacteria are generated.

[4] "Expression" of a gene refers to the production of the protein which the gene encodes; more specifically, it is the process of transferring information from a gene (which consists of DNA) via messenger RNA to ribosomes where a specific protein is made.

[5] In the context of the claimed invention, "selectable markers" or "marker genes" refer to antibiotic-resistance conferring DNA fragments, attached to the gene being expressed, which facilitate the selection of successfully transformed cyanobacteria.

[6] 12 *Nucleic Acids Res.* 8917 (1984).

[7] Chloramphenicol is an antibiotic; CAT is an enzyme which destroys chloramphenicol and thus imparts resistance thereto.

Sekar I,[8] Sekar II,[9] and Ganesan [10] collectively disclose expression of genes encoding certain *Bacillus* insecticidal proteins in the bacterial hosts *B. megaterium*, *B. subtilis* and *E. coli*.

Friedberg [11] discloses the transformation of the cyanobacterium *Anacystis nidulans* R2 by a plasmid vector comprising the O_LP_L operator-promoter region and a temperature-sensitive repressor gene of the bacteriophage Lambda. While the cyanobacteria are attractive organisms for the cloning of genes involved in photosynthesis, Friedberg states, problems may still be encountered such as suboptimal expression of the cloned gene, detrimental effects on cell growth of overexpressed, highly hydrophobic proteins, and rapid turnover of some gene products. To address these problems, Friedberg teaches the use of the disclosed Lambda regulatory signals in plasmid vehicles which, it states, have "considerable potential for use as vectors the expression of which can be controlled in *Anacystis*. . . ."

Miller [12] compares the initiation specificities *in vitro* of DNA-dependent RNA polymerases [13] purified from two different species of cyanobacteria (*Fremyella diplosiphon* and *Anacystis nidulans*), as well as from *E. coli*.

Nierzwicki-Bauer [14] identifies in the cyanobacterium *Anabaena* 7120 the start site for transcription of the gene encoding *rbc*L, the large subunit of the enzyme ribulose-1, 5-bisphosphate carboxylase. It reports that the nucleotide sequence 14-8 base pairs preceding the transcription start site "resembles a good *Escherichia coli* promoter," but that the sequence 35 base pairs before the start site does not.

Chauvat [15] discloses host-vector systems for gene cloning in the cyanobacterium *Synechocystis* 6803, in which the antibiotic resistance-conferring *neo* gene is utilized as a selectable marker.

Reiss [16] studies expression in *E. coli* of various proteins formed by fusion of certain foreign DNA sequences with the *neo* gene.

Kolowsky [17] discloses chimeric plasmids designed for transformation of the cyanobacterium *Synechococcus* R2, comprising an antibiotic-resistant gene linked to chromosomal DNA from the *Synechococcus* cyanobacterium.

Barnes, United States Patent No. 4,695,455, is directed to the treatment with stabilizing chemical reagents of pesticides produced by expression of heterologous genes (such as those encoding *Bacillus* proteins) in host microbial cells such as *Pseudomonas* bacteria. The host cells are killed by this treatment, but the resulting pesticidal compositions exhibit prolonged toxic activity when exposed to the environment of target pests.

D. *The Grounds of Rejection*

1. The § 103 Rejections

Claims 1-6, 16-21, 33-38, 47-48 and 52 (which include all independent claims in the application) were rejected as unpatentable under 35 USC 103 based upon Dzelzkalns in view of Sekar I or Sekar II and Ganesan. The examiner stated that Dzelzkalns discloses a chimeric gene capable of being highly expressed in a cyanobacterium, said gene comprising a promoter region effective for expression in a cyanobacterium operably linked to a structural gene encoding CAT. The examiner acknowledged that the chimeric gene and transformed host of Dzelzkalns differ from the claimed invention in that the former's structural gene encodes CAT rather than insecticidally active protein. However, the examiner pointed out, Sekar I, Sekar II, and Ganesan teach genes encoding insecticidally active proteins produced by *Bacillus*, and the advantages of expressing such genes in heterologous [18] hosts to obtain larger quantities of the protein. The examiner contended that it would have been obvious to one of ordinary skill in the art to substitute the *Bacillus* genes taught by Sekar I, Sekar II, and Ganesan for the CAT gene in the vectors of Dzelzkalns in order to obtain high level expression of the *Bacillus* genes in the transformed cyanobacteria. The examiner further contended that it would have been obvious to use cyanobacteria as heterologous hosts for expression of the claimed genes due to the ability of cyanobacteria to serve as transformed hosts for the

[8] 137 *Biochem. and Biophys. Res. Comm.* 748 (1986).

[9] 33 *Gene* 151 (1985).

[10] 189 *Mol. Gen. Genet.* 181 (1983).

[11] 203 *Mol. Gen. Genet.* 505 (1986).

[12] 140 *J. Bacteriology* 246 (1979).

[13] RNA polymerase, the enzyme responsible for making RNA from DNA, binds at specific nucleotide sequences (promoters) in front of genes in DNA, and then moves through the gene making an RNA molecule that includes the information contained in the gene. Initiation specificity is the ability of the RNA polymerase to initiate this process specifically at a site(s) on the DNA template.

[14] 81 *Proc. Natl. Acad. Sci. USA* 5961 (1984).

[15] 204 *Mol. Gen. Genet.* 185 (1986).

[16] 30 *Gene* 211 (1984).

[17] 27 *Gene* 289 (1984).

[18] Denotes different species or organism.

expression of heterologous genes. In the absence of evidence to the contrary, the examiner contended, the invention as a whole was prima facie obvious.

Additional rejections were entered against various groups of dependent claims which we need not address here. All additional rejections were made in view of Dzelzkalns in combination with Sekar I, Sekar II, and Ganesan, and further in view of other references discussed in Part C above.

The Board affirmed the § 103 rejections, basically adopting the examiner's Answer as its opinion while adding a few comments. The legal conclusion of obviousness does not require absolute certainty, the Board added, but only a reasonable expectation of success, citing *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). In view of the disclosures of the prior art, the Board concluded, one of ordinary skill in the art would have been motivated by a reasonable expectation of success to make the substitution suggested by the examiner.

2. The § 112 Rejection

The examiner also rejected claims 1-48 and 50-51 under 35 USC 112, first paragraph, on the ground that the disclosure was enabling only for claims limited in accordance with the specification as filed. Citing *Manual of Patent Examining Procedure* (MPEP) provisions 706.03(n) [19] and (z) [20] as support, the examiner took the position that undue experimentation would be required of the art worker to practice the claimed invention, in view of the unpredictability in the art, the breadth of the claims, the limited number of working examples and the limited guidance provided in the specification. With respect to unpredictability, the examiner stated that

> [t]he cyanobacteria comprise a large and diverse group of photosynthetic bacteria including large numbers of species in some 150 different genera including *Synechocystis, Anacystis, Synechococcus, Agmenellum, Nostoc, Anabaena*, etc. The molecular biology of these organisms has only recently become the subject of intensive investigation and this work is limited to a few genera. Therefore the level of unpredictability regarding heterologous gene expression in this large, diverse and relatively poorly studied group of procaryotes is high.

The Board affirmed, noting that "the limited guidance in the specification, considered in light of the relatively high degree of unpredictability in this particular art, would not have enabled one having ordinary skill in the art to practice the broad scope of the claimed invention without undue experimentation. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)."

OPINION

A. *Obviousness*

We first address whether the PTO erred in rejecting the claims on appeal as prima facie obvious within the meaning of 35 USC 103. Obviousness is a legal question which this court independently reviews, though based upon underlying factual findings which we review under the clearly erroneous standard. *In re Woodruff*, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990).

[1] Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *See In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. *Id.*

[19] MPEP 706.03(n), "Correspondence of Claim and Disclosure," provides in part:

> In chemical cases, a claim may be so broad as to not be supported by [the] disclosure, in which case it is rejected as unwarranted by the disclosure. . . .

[20] MPEP 796.03(z), "Undue Breadth," provides in part:

> [I]n applications directed to intentions in arts were the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Sol*, 1938 C.D. 723; 497 O.G. 546. This is because in arts such as chemistry it is not obvious from the disclosure of one species, what other species will work. *In re Dreshfield*, 1940 C.D. 351; 518 O.G. 255 gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

[2] We agree with appellants that the PTO has not established the prima facie obviousness of the claimed subject matter. The prior art simply does not disclose or suggest the expression in cyanobacteria of a chimeric gene encoding an insecticidally active protein, or convey to those of ordinary skill a reasonable expectation of success in doing so. More particularly, there is no suggestion in Dzelzkalns, the primary reference cited against all claims, of substituting in the disclosed plasmid a structural gene encoding *Bacillus* insecticidal proteins for the CAT gene utilized for selection purposes. The expression of antibiotic resistance-conferring genes in cyanobacteria, without more, does not render obvious the expression of unrelated genes in cyanobacteria for unrelated purposes.

The PTO argues that the substitution of insecticidal *Bacillus* genes for CAT marker genes in cyanobacteria is suggested by the secondary references Sekar I, Sekar II, and Ganesan, which collectively disclose expression of genes encoding *Bacillus* insecticidal proteins in two species of host *Bacillus* bacteria (*B. megaterium* and *B. subtilis*) as well as in the bacterium *E. coli*. While these references disclose expression of *Bacillus* genes encoding insecticidal proteins in certain transformed *bacterial* hosts, nowhere do these references disclose or suggest expression of such genes in transformed *cyanobacterial* hosts.

To remedy this deficiency, the PTO emphasizes similarity between bacteria and cyanobacteria, namely, that these are both procaryotic organisms, and argues that this fact would suggest to those of ordinary skill the use of cyanobacteria as hosts for expression of the claimed chimeric genes. While it is true that bacteria and cyanobacteria are now both classified as procaryotes, that fact alone is not sufficient to motivate the art worker as the PTO contends. As the PTO concedes, cyanobacteria and bacteria are not identical; they are classified as two separate divisions of the kingdom Procaryotae.[21] Moreover, it is only in recent years that the biology of cyanobacteria has been clarified, as evidenced by references in the prior art to "blue-green algae." Such evidence of recent uncertainty regarding the biology of cyanobacteria tends to rebut, rather than support, the PTO's position that one would consider the cyanobacteria effectively interchangeable with bacteria as hosts for expression of the claimed gene.

At oral argument the PTO referred to additional secondary references, not cited against any independent claim (i.e., Friedberg, Miller, and Nierzwicki-Bauer), which it contended disclose certain amino acid sequence homology between bacteria and cyanobacteria. The PTO argued that such homology is a further suggestion to one of ordinary skill to attempt the claimed invention. We disagree. As with the Dzelzkalns, Sekar I, Sekar II, and Ganesan references discussed above, none of these additional references disclose or suggest that cyanobacteria could serve as hosts for expression of genes encoding *Bacillus* insecticidal proteins. In fact, these additional references suggest as much about *differences* between cyanobacteria and bacteria as they do about similarities. For example, Nierzwicki-Bauer reports that a certain nucleotide sequence (i.e., the -10 consensus sequence) in a particular cyanobacterium resembles an *E. coli* promoter, but that another nearby nucleotide sequence (the -35 region) does not. While Miller speaks of certain promoters of the bacteriophage Lambda that are recognized by both cyanobacterial and *E. coli* RNA polymerases, it also discloses that these promoters exhibited differing strengths when exposed to the different polymerases. Differing sensitivities of the respective polymerases to an inhibitor are also disclosed, suggesting differences in the structures of the initiation complexes.

The PTO asks us to agree that the prior art would lead those of ordinary skill to conclude that cyanobacteria are attractive hosts for expression of any and all heterologous genes. Again, we can not. The relevant prior art does indicate that cyanobacteria are attractive hosts for expression of both native and heterologous *genes involved in photosynthesis* (not surprisingly, for the capability of undergoing oxygenic photosynthesis is what makes the cyanobacteria unique among procaryotes). However, these references do not suggest that cyanobacteria would be equally attractive hosts for expression of *unrelated* heterologous genes, such as the claimed genes encoding *Bacillus* insecticidal proteins.

In *O'Farrell*, this court affirmed an obviousness rejection of a claim to a method for

[21] *Stedman's Medical Dictionary* 1139 (24th ed. 1982) (definition of "Procaryotae"). Procaryotic organisms are commonly classified according to the following taxonomic hierarchy: Kingdom; Division; Class; Order; Family; Genus; Species. 3 *Bergey's Manual of Systematic Bacteriology* 1601 (1989).

producing a "predetermined protein in a stable form" in a transformed bacterial host. 853 F.2d at 895, 7 USPQ2d at 1674. The cited references included a prior art publication (the Polisky reference) whose three authors included two of the three coinventor-appellants. The main difference between the prior art and the claim at issue was that in Polisky, the heterologous gene was a gene for ribosomal RNA, while the claimed invention substituted a gene coding for a predetermined protein. *Id.* at 901, 7 USPQ2d at 1679. Although, as the appellants therein pointed out, the ribosomal RNA gene is not normally translated into protein, Polisky mentioned preliminary evidence that the transcript of the ribosomal RNA gene was translated into protein, and further predicted that if a gene coding for a protein were to be substituted, extensive translation might result. *Id.* We thus affirmed, explaining that

> the prior art explicitly suggested the substitution that is the difference between the claimed invention and the prior art, and presented preliminary evidence suggesting that the [claimed] method could be used to make proteins.
>
> . . . Polisky contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful.

Id. at 901-02, 7 USPQ2d at 1679-80.

In contrast with the situation in *O'Farrell*, the prior art in this case offers no suggestion, explicit or implicit, of the substitution that is the difference between the claimed invention and the prior art. Moreover, the "reasonable expectation of success" that was present in *O'Farrell* is not present here. Accordingly, we reverse the § 103 rejections.

B. *Enablement*

[3] The first paragraph of 35 USC 112 requires, *inter alia*, that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without "undue experimentation." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is "undue." *Id.* at 736-37, 8 USPQ2d at 1404. Enablement, like obviousness, is a question of law which we independently review, although based upon underlying factual findings which we review for clear error. *See id.* at 735, 8 USPQ2d at 1402.

In response to the § 112 rejection, appellants assert that their invention is "pioneering," and that this should entitle them to claims of broad scope. Narrower claims would provide no real protection, appellants argue, because the level of skill in this art is so high, art workers could easily avoid the claims. Given the disclosure in their specification, appellants contend that any skilled microbiologist could construct vectors and transform many different cyanobacteria, using a variety of promoters and *Bacillus* DNA, and could easily determine whether or not the active *Bacillus* protein was successfully expressed by the cyanobacteria.

The PTO made no finding on whether the claimed invention is indeed "pioneering," and we need not address the issue here. With the exception of claims 47 and 48, the claims rejected under § 112 are not limited to any particular genus or species of cyanobacteria. The PTO's position is that the cyanobacteria are a diverse and relatively poorly studied group of organisms, comprising some 150 different genera, and that heterologous gene expression in cyanobacteria is "unpredictable." Appellants have not effectively disputed these assertions. Moreover, we note that only one particular species of cyanobacteria is employed in the working examples of appellants' specification, and only nine genera of cyanobacteria are mentioned in the entire document.

[4] Taking into account the relatively incomplete understanding of the biology of cyanobacteria as of appellants' filing date, as well as the limited disclosure by appellants of particular cyanobacterial genera operative in the claimed invention, we are not persuaded that the PTO erred in rejecting claims 1-46 and 50-51 under § 112, first paragraph. There is no reasonable correlation between the narrow disclosure in appellants' specification and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria. *See In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (the first paragraph of § 112 requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification).[22] Accordingly, we affirm the § 112 rejection as to those claims.

In so doing we do *not* imply that patent applicants in art areas currently denominated as "unpredictable" must never be allowed generic claims encompassing more than the particular species disclosed in their specification. It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Angstadt*, 537 F.2d 498, 502-03, 190 USPQ 214, 218 (CCPA 1976). However, there must be sufficient disclosure, either through illustrative examples or terminology,[23] to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element. *See Fisher*, 427 F.2d at 839, 166 USPQ at 24. In this case, we agree with the PTO that appellants' limited disclosure does not enable one of ordinary skill to make and use the invention as now recited in claims 1-46 and 50-51 without undue experimentation.

Remaining dependent claim 47 recites a cyanobacterium which expresses the chimeric gene of claim 1, wherein the cyanobacterium is selected from among the genera *Anacystis* and *Synechocystis*. Claim 48, which depend from claim 47, is limited to the cyanobacterium *Synechocystis* 6803. The PTO did not separately address these claims, nor indicate why they should be treated in the same manner as the claims encompassing all types of cyanobacteria. Although these claims are not limited to expression of genes encoding particular *Bacillus* proteins, we note what appears to be an extensive understanding in the prior art of the numerous *Bacillus* proteins having toxicity to various insects. The rejection of claims 47-48 under § 112 will not be sustained.

[22] The enablement rejection in this case was not based upon a post-filing date state of the art, as in *In re Hogan*, 559 F.2d 595, 605-07, 194 USPQ 527, 536-38 (CCPA 1977). *See also United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed. Cir. 1989) (citing *Hogan*); *Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1568-69, 15 USPQ2d 1039, 1047-48 (Fed. Cir. 1990) (directing district court, on remand, to consider effect of *Hogan* and *United States Steel* on the enablement analysis of *Fisher*), *cert. dismissed*, ____ U.S. ____, 111 S. Ct. 1434 (1991). We therefore do not consider the effect of *Hogan* and its progeny on *Fisher*'s analysis of when an inventor should be allowed to "dominate the future patentable inventions of others." *Fisher*, 427 F.2d at 839, 166 USPQ at 24.

[23] The first paragraph of § 112 requires nothing more than *objective* enablement. *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is irrelevant. *Id.*

CONCLUSION

The rejection of claims 1-48 and 50-52 under 35 USC 103 is *reversed*. The rejection of claims 1-46 and 50-51 under 35 USC 112, first paragraph, is *affirmed* and the rejection of claims 47 and 48 thereunder is *reversed*.

AFFIRMED-IN-PART, REVERSED-IN-PART

Mayer, J., dissenting.

An appeal is not a second opportunity to try a case or prosecute a patent application, and we should not allow parties to "undertake to retry the entire case on appeal." *Perini America, Inc. v. Paper Converting Machine Co.*, 832 F.2d 581, 584, 4 USPQ2d 1621, 1624 (Fed. Cir. 1987); *Eaton Corp. v. Appliance Valves Corp.*, 790 F.2d 874, 877, 229 USPQ 668, 671 (Fed. Cir. 1986). But that is precisely what the court has permitted here. The PTO conducted a thorough examination of the prior art surrounding this patent application and concluded the claims would have been obvious. The board's decision based on the examiner's answer which comprehensively explains the rejection is persuasive and shows how the evidence supports the legal conclusion that the claims would have been obvious. Yet, the court ignores all this and conducts its own examination, if you will, as though the examiner and board did not exist. Even if I thought this opinion were more persuasive than the board's, I could not join it because it misperceives the role of the court.

The scope and content of the prior art, the similarity between the prior art and the claims, the level of ordinary skill in the art, and what the prior art teaches are all questions of fact. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966); *Jurgens v. McKasy*, 927 F.2d 1552, 1560, 18 USPQ2d 1031, 1037 (Fed. Cir. 1991). And "[w]here there are two permissible views of

the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson v. City of Bessemer City*, 470 U.S. 564, 574 (1985). The mere denomination of obviousness as a question of law does not give the court license to decide the factual matters afresh and ignore the requirement that they be respected unless clearly erroneous. *In re Woodruff*, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990); *In re Kulling*, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1057 (Fed. Cir. 1990). There may be more than one way to look at the prior art, but on this record we are bound by the PTO's interpretation of the evidence because it is not clearly erroneous and its conclusion is unassailable. I would affirm on that basis.

Court of Appeals, Federal Circuit

Biocraft Laboratories Inc. v. International Trade Commission

Nos. 91-1153, 1208

Decided October 17, 1991

PATENTS

1. U.S. International Trade Commission — Remedies (§155.07)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Settlement agreements; consent decrees (§410.43)

REMEDIES

Non-monetary and injunctive — Equitable relief — Preliminary injunctions — Bond (§505.0707.03)

International Trade Commission abused its discretion by refusing to release bond posted by respondent to 19 USC 1337 complaint in compliance with temporary cease and desist order, even though respondent made sales of infringing product during effective period of order, since complainant authorized sales in question and agreed to return of bond as part of settlement agreement with respondent, since bond provisions, under terms of order, do not apply to sales authorized by complainant, and since public interest in vindicating rights of patentees, as well as complainant's interest in offsetting competitive advantage respondent obtained by importing infringing product, were satisfied by complainant's agreement to return of bond and thus would not be furthered by retention of bond by ITC.

Appeal from the U.S. International Trade Commission.

U.S. International Trade Commission investigation no. 337-TA-293, instituted in response to complaint of Bristol-Meyers Co., now Bristol-Meyers Squibb Co., against, inter alia, Biocraft Laboratories Inc., for violation of Tariff Act's Section 337, 19 USC 1337. From order denying in part respondent's request for return or cancellation of two bonds posted in compliance with temporary cease and desist order, and from order denying respondent's request for reconsideration of prior order, respondent appeals. Reversed.

Prior decision: 15 USPQ2d 1258.

Marc S. Gross, of Bryan, Cave, McPheeters & McRoberts (Michael G. Biggers, Elizabeth C. Carver, David A. Roodman, and Elizabeth M. Garnhard, on brief), New York, N.Y., for appellant.

Marc A. Bernstein (Lyn Schlitt, general counsel, and James A. Toupin, assistant general counsel, on brief), for appellee.

Before Skelton, senior circuit judge, and Newman and Lourie, circuit judges.

Lourie, J.

This is a consolidated appeal from (1) an order of the United States International Trade Commission issued November 14, 1990, in *Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, No. 91-1153, denying in part Biocraft Laboratories, Inc.'s request for return or cancellation of two bonds and (2) an order of the Commission issued January 11, 1991, Inv. No. 337-TA-293, No. 91-1208, denying Biocraft's request for reconsideration of the prior order. Because we conclude that the Commission's denial of Biocraft's requests was an abuse of discretion, we *reverse*.

BACKGROUND

This appeal stems from an investigation begun by the Commission in response to a complaint and motion for temporary relief filed by the Bristol-Myers Company[1] on February 1, 1989. In the complaint, Bristol alleged that Biocraft, among other firms, was violating section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, by importing and selling crystalline cefadroxil monohydrate (cefadroxil), an antibiotic covered by Bristol's U.S. Patent 4,504,657 ("the '657 patent"). Biocraft was named one of the respondents in the Commission's investigation. After an initial determination denying Bristol's motion for temporary relief on May 13, 1989, and a subsequent refusal to modify or vacate the initial determination, this court determined that the validity of the '657 patent was likely to be sustained and reversed the Commission's determination. *Bristol-Myers Co. v. United States Int'l Trade Comm'n*, 15 USPQ2d 1258 (Fed. Cir. 1989) (the Commission exceeded its discretionary authority, committed an error of law, and seriously misjudged the evidence by refusing to grant temporary relief under 19 U.S.C. § 1337 (e)(3) where there was reason to believe that there was a violation of section 337).

On January 10, 1990, the Commission issued a temporary cease and desist order against Biocraft. Paragraph III of the Order listed the conduct prohibited by Biocraft, stating that

> Respondent shall not market, distribute, offer for sale, sell, or otherwise transfer in the United States imported crystalline cefadroxil monohydrate that infringes claim 1 of U.S. Letters Patent 4,504,657, except under license of the patent owner.

The Order required that Biocraft post a bond with the Commission to allow the sale of previously imported cefadroxil. Specifically, Paragraph XI of the Order stated:

> With respect to crystalline cefadroxil monohydrate imported prior to January 10, 1990, the conduct prohibited by paragraph III of this Order may be continued during the period in which this order is in effect subject to Respondent posting a bond in the amount of sixty-eight (68) percent of the entered value of crystalline cefadroxil monohydrate capsules or bulk powder in question. *This bond provision does not apply to conduct which is otherwise permitted by paragraph IV of this Order.*

(Emphasis added). Paragraph XI further stated the conditions for forfeiture or release of the bond.[2] The conduct specifically allowed by Biocraft is recited in Paragraph IV, which provides that

> [n]otwithstanding any other provisions of this Order, specific conduct otherwise prohibited by the terms of this Order, shall be permitted if, in a written instrument, such specific conduct *is licensed or authorized* by Complainant or related to the importation or sale of crystalline cefadroxil monohydrate thereof by or for the United States.

(Emphasis added). Biocraft did not appeal this order, but pursuant thereto, posted two bonds with the Commission, on January 19 and January 25, 1990, totalling $705,000.

The Commission concluded its section 337 investigation on March 15, 1990, issuing a permanent cease and desist order against Biocraft and determining that the '657 patent was valid and enforceable and had been infringed. Biocraft did not appeal this decision. The permanent relief order became final on May 14, 1990, at the end of the 60-day period in which the President could have disapproved the Commission's order.[3]

On March 29, 1990, Bristol and Biocraft settled their separate district court litigation concerning validity and infringement of the '657 patent. The settlement agreement required Biocraft to pay Bristol $21,000,000. Additionally, the agreement provided that

> Bristol-Myers will, if requested by Biocraft, join in any petition by Biocraft to obtain a return or discharge of the bond posted by Biocraft with the ITC, and Bristol-Myers will state that it is joining in and/or supporting such request as a result of a settlement with Biocraft.

Subsequently, on April 23, 1990, Biocraft requested that the Commission return the bonds. Pursuant to the settlement agreement, Bristol submitted a letter joining Biocraft's petition. The Commission investigative attorney opposed the petition.

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[1] The Bristol-Myers Company has since become the Bristol-Myers Squibb Company.

[2] The bond is to be forfeited in the event that the President approves, or does not disapprove within the Presidential review period, the Commission's Orders of January 10, 1990, or any subsequent final order issued after the completion of Investigation No. 337-TA-293, unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or unless Respondent exports the products subject to this bond or destroys them and provides certification to that effect satisfactory to the Commission.

This bond is to be released in the event the President disapproves this Order and no subsequent order is issued by the Commission and approved, or not disapproved, by the President, upon service on Respondent of an Order issued by the Commission based upon application therefor made by Respondent to the Commission.

[3] *See* 19 U.S.C. § 1337(j)(3).